ASPIRA WOMEN'S HEALTH INC.

FORM 10-K
(Annual Report)

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

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, 201 4 .

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission f ile n umber: 001-34810

Vermillion, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0595156**
(State or O ther J urisdiction of I ncorporation or O rganization)	(I.R.S. Employer Identification No.)

12117 Bee Caves Road, Building T hree , Suite 100

Austin, Texas	**78738**
(Address of P rincipal E xecutive O ffices)	(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	Name of each exchan ge on which registered
Common Stock, par value $0.001 per share	**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 wa s required to file such reports) , and (2) has been subject to such filing requ irements 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 Dat a 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 definition s 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 - accel e rated 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 r egistrant is $ 50,201, 743

and is based upon the last sales price as quoted on T he NASDAQ Capital Market as of June 30, 201 4 .

As of March 2 4 , 201 5 , the r egistrant had 43,115 , 790 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Ce rtain information from the registrant's definitive Proxy Statement for its Annual Meeting of Stockholders, scheduled to be held on June 1 8 , 201 5 , 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, 2014 .

VERMILLION, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 201 4

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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 , except as required by law, 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 or expectations regarding our future revenue, results of operations and financial condition;
- o ur plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders;
- intentions to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and other issues in the fields of oncology and women’s health;
- 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;
- plans with respect to ASPiRA LABS, Inc. (“ASPiRA LABS”) , including obtaining state licensure ;
- p lans with respect to OVA2 and OvaX;
- p lans to develop and implement laboratory development tests (“LDTs”) at ASPiRA LABS;
- 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, pending and future regulatory or scientific submissions and presentations;
- our continued ability to comply with applicable governmental regulations;
- o ur ability to obtain and maintain the regulatory approvals required to market OVA1 in other countries;
- 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 ;
- anticipated 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 of 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") , including ASPiRA LABS ; 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; in the event that we succeed in commercializing OVA1 outside the United States , the political, economic and other conditions affecting other countries (including foreign exchange rates) ; 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 required for our future diagnostic products; our or our suppliers' ability to comply with FDA requirements for production, marketing and post - market 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 ; our ability to generate sufficient demand for ASPiRA LABS' services to cover it s operating costs; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; our ability to obtain any FDA clearance or approval required to develop and perform LDTs ; 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 .

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 disease – both benign and malignant cancers as well as other gynecologic diseases.

We have expanded our corporate strategy with the goal of transforming Vermillion from a technology license company to a diagnostic service and bio-analytic solutions provider. Our plan is to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders . Our strategy will be deployed in three phases. The three phases are a rebuild phase , which we expect to complete i n Q2 2015, a transformation phase , which is ongoing and is expected to span 2015 , and a market expansion and growth phase, which we expect to begin in 2016.

During the first phase, we expanded our leadership team by hiring new heads of sales and customer experience, managed markets, marketing , operations, a chief medical officer and a chief executive officer. In addition, we expanded our commercial strategy, reestablished medical and advisory support, rebuilt our patient advocacy strategy and established a billing system and a payer strategy outside of our relationship with Quest Diagnostics. During the second phase, we plan to obtain licensure of ASPiRA LABS in all 50 states, establish our own payer coverage for OVA1 and launch a second-generation OVA1 test, known as OVA2 (predicated on receipt of FDA approval). In the third phase we plan to commercialize OVA2 by utilizing the full national licensure of ASPiRA LABS, managed care coverage in select markets, our sales force and existing customer base . Unlike OVA1, OVA2 uses a global testing platform, which will allow OVA2 to be deployed internationally. We also plan to demonstrate proof of concept for a LDT product series, which we refer to internally as OvaX. We anticipate that OvaX will include not only biomarkers, but also clinical risk factors and patient history data in order to boost predictive value.

Mission Statement: We are dedicated to the discovery, development and commercialization of novel high-value diagnostic and bio-analytical solutions that help physicians diagnose, treat and improve outcomes for women . Our tests are intended to detect, characterize and stage disease, and to help guide decisions regarding patient treatment , which may include decisions to refer patients to specialists, to perform additional testing, or to assist in monitoring response to therapy. A distinctive feature of our approach is to combine multiple bio markers , other modalit ies and diagnostics , clinical risk factors and patient data into a single, reportable index score that has higher diagnostic accuracy than its constituents. We concentrate our development of novel diagnostic tests for gyne cologic disease , 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 clinical research institutions.

Strategy:

W e are focused on the execution of four 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 by expanding our direct market reach beyond our current commercial agreement with Quest Diagnostics and taking the lead in payer coverage and commercialization of

OVA1. This strategy includes the launch of a Clinical Laboratory Improvement Amendments of 1988 (“ CLIA ”) certified clinical laboratory, ASPiRA LABS , in June 2014;

- Improving OVA1 performance by seeking FDA clearance of a potentially better performing biomarker panel while migrating OVA1 to a global testing platform , thus allowing for better domestic market penetration and international expansion;

- Building an expanded patient base by launching a next generation multi-marker ovarian cancer test to monitor patients at risk for ovarian cancer ; and

- Expanding our product offerings by adding additional gynecologic bio-analytic solutions involving biomarkers, other modalities (e.g. , imaging), clinical risk factors and patient data to aid diagnosis and risk stratification of women presenting with a pelvic mass disease.

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

Business:

Our lead product, OVA1, is a blood test designed to identify women who are at high risk of having a malignant ovarian tumor prior to surgery. The FDA cleared OVA1 in September 2009 and we commercially launched OVA1 in March 2010. We have completed development and validation work on a second-generation biomarker panel intended to maintain our product’s high sensitivity while improving specificity. We submitted our 510(k) clearance applicat ion to the FDA o n March 6, 2015 , with the goal of commencing the marketing and sale of the panel in the second half of 2015. The product use s the Roche Cobas platform .

OVA1 addresses a clear clinical need, namely the presurgical 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 presurgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary software cleared as part of the OVA1 510(k) to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary testing, surgery and/or delayed diagnosis. 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 June 2014, Vermillion launched ASPiRA LABS, a CLIA certified national laboratory based near Austin, Texas, which specializes in applying biomarker-based technologies, to address critical needs in the management of gynecologic cancers. ASPiRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based diagnostic algorithm to inform clinical decision making and advance personalized treatment plans. In addition, ASPiRA LABS, seeks to serve as an educational and resource hub for healthcare professionals and women facing surgery for potentially-cancerous ovarian masses and other related gynecologic conditions. The lab currently processes our OVA1 test, and we expect the lab to process the CA 125II test in the future in specific markets . We plan to expand the testing provided to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPiRA LAB S . ASPiRA LABS currently holds a temporary CLIA Certificate of Registration and a state laboratory license in California and Rhode Island. ASPiRA LABS is in the process of obtaining a full Certificate of Accreditation and state laboratory licensure in New York, Florida, Maryland and Pennsylvania. The Centers for Medicare and Medicaid Services (“CMS”) issued a provider number to A SPiRA LABS on Mar ch 5 , 2015.

We terminated our Strategic Alliance Agreement with Quest Diagnostics (the “Strategic Alliance Agreement”) in August 2013 . Prior to the termination of the Strategic Alliance Agreement , Quest Diagnostics had the right to be the exclusive clinical reference laboratory marketplace provider of OVA1 tests in its exclusive territory, which included the United States, Mexico, the United Kingdom and India. As part of the termination, we agreed that Quest Diagnostics could continue to make OVA1 available to healthcare providers under legacy financial terms following the termination while negotiating in good faith towards an alternative business structure . Quest Diagnostics disputed the effectiveness of such termination.

As a result of ongoing negotiations, on March 11, 2015, we reached a settlement agreement with Quest Diagnostics that terminated all disputes related to our prior strategic alliance and loan agreements. We also entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement , Vermillion’s wholly-owned subsidiary , ASPiRA LABS, will begin to offer OVA1 testing to Quest Diagnostics customers. We expect Quest Diagnostics to transfer all OVA1 U.S. testing services to ASPiRA LABS, starting with 39 states this year, while continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing for a period of two years from the date of the agreement. Pursuant to the agreement, Quest

Diagnostics will also continue to offer OVA1 services through its own labs in the remaining 11 states , until ASPiRA LABS has obtained the state approvals required to provide those services. Quest will receive a fee for collection and logistic support services it provides . Per the terms of the agreement, we will not offer to existing or future Quest Diagnostics customers CA 125 - II or other tests that Quest Diagnostics offers.

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 reflecti ng 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 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 U niversity 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 United States . 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 .

O f 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 difference s 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). O verall prevalence of malignancy in the OVA500 study was 18.6% overall (92/494) and 11.2% (31/277) in premenopausal surgery patients. Th ese malignancy rate s w ere 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 oncologist s , 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 the 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 o nly 37 % 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 presurgical 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 % survived at least five years if their care met the guidelines, compared with 25 % of those whose care fell short.

Results of this study w ere 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 guidelines for evaluation of suspicious pelvic masses.

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 clinical study published in *The American Journal of Obstetrics & Gynecology* reported superior sensitivity of OVA1 for presurgical triage of ovarian cancer, compared with commonly used risk assessment methods. [5] The 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 with rates predicted from clinical assessment, OVA1, CA125 or from the modified-American College of Obstetricians and Gynecologists guidelines.

Dr. Robert 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.

I n March 2014, we announced that a study of OVA1® clinical performance, titled "The Effect of Ovarian Imaging on the Clinical Interpretation of a Multivariate Index Assay," was 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. We view this study as an initial proof of concept for our planned OvaX products.

"This new study advances our understanding of how OVA1 and imaging work together in the presurgical 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 - 90 % . 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 clinica l 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 May 2014, we announced a Vermillion - funded study with Moffitt Cancer Center in Tampa, Fl orida. The purpose of the study is to produce clinical and economic data to support a new value-based practice model that may improve survival, quality of life and cost-effectiveness of care for patients with ovarian cancer. It features two phases . The first phase will be retrospective, and will benchmark the care standards and variances provided to patients with ovarian, fallopian tube and/or primary peritoneal cancer. The second phase will model improvements in care quality and cost that may be afforded by creating a standardized triage algorithm employing different FDA-cleared or prototype multi-marker blood tests, along with established clinical diagnostic or prognostic factors such as pelvic exams and ultrasound imaging.

In May 2013, the SGO issued a 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 presurgically 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 ACOG ’ s 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. ”

We believe the position statement does two things:

1. 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.
2. 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 .

On March 27, 2015, initial results from a cost-effectiven ess analysis study w ere presented at the Annual Meeting of the American College of Medical Quality in Alexandria, Virginia. The study was co-authored by Dr. Robert E. Bristow and Dr. Gareth K. Forde, clinicians at the University of California at Irvine (“ UC Irvine ”), and Dr. John Hornberger, a leading health economist at Stanford University School of Medicine. This new study, entitled: “Cost Effectiveness Analysis of a Multivariate Index Assay compared to Modified ACOG Criteria and CA-125 in the Triage of Women with Adnexal Masses”, further establishes important advantages that OVA1 may provide in the detection, triage and cost-effective management of ovarian cancer.

The study compared clinical outcomes and costs using OVA1 versus the off-label but commonly used CA-125 (" CA 125-II "), an ovarian cancer biomarker, or current gynecologic best-practice care known as Dearking-modified ACOG guidelines (" mod-ACOG "). Model endpoints included overall survival, costs, quality-adjusted life years (" QALY ") and incremental cost effectiveness ratio. The analysis considered a lifetime horizon from the standpoint of a public payer (using Medicare reimbursement rates) and an accepted cost-effectiveness threshold of $50,000 per QALY.

Several important health economic and quality outcomes conclusions were reported in the new study:

- Use of OVA1 resulted in fewer projected re-operations and pre-treatment CT scans versus CA 125-II or mod-ACOG ,
- OVA1 was QALY-increasing and cost-effective relative to CA 125-II or mod-ACOG ,
- ICERs of $12,189/QALY and $35,094/QALY were calculated for OVA1 versus CA 125-II and mod-ACOG, respectively; resulting in a "cost-effective" outcome based on the $50,000 threshold , and
- Relative to the best-practice mod-ACOG benchmark, OVA1 projected an annual increase in patient survival and QALY in excess of 1,000 years, when the surgical cohort was projected to national annual adnexal mass surgeries including about 22,000 new cases of ovarian cancer

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; the University of Kentucky ("UK") and UC Irvine .

The Diagnostic M arket

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. Visiongain , an independent business information provider, predict ed that the worldwide market for in vitr o diagnostics (" IVDs ") would 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 s, and provider and patient relationships . Demographic trends suggest that, as the population ages, the burden from gynecologic diseases, including 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 has allowed and will continue to 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 IVD MIA (also known as In Vitro Diagnostic Multiv ariate Index Assays), and often utilize advanced algorithms based on logistic regression, pattern recognition and the like. Often, IVDMIA 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 needed 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 over 2 1 ,000 new ovarian cancer cases will be diagnosed in 201 5 , with greater than 75% of the patients diagnosed 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 high mortality rates.

According to the A CS , 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, there is a clinical need for 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 % . A dnexal 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. According to 2010 U . S . census data, there are 36.8 million women between the age s of 50 and 70 in the U.S. , suggesting that there are more than 1.7 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 overall .

Commercialization

We offer OVA1 both through Quest Diagnostics as well as ASPiRA LABS. As a result of ongoing negotiations, on March 11, 2015, we reached a settlement agreement with Quest Diagnostics that terminated all disputes related to our prior strategic alliance and loan agreements. We also entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, Vermillion's wholly-owned subsidiary, ASPiRA LABS , will begin to offer OVA1 testing to Quest Diagnostics customers. We expect Quest Diagnostics to transfer all OVA1 U.S. testing services to ASPiRA LABS, starting with 39 states this year, while continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing for a period of two years from the date of the agreement . Pursuant to the agreement, Quest Diagnostics will also continue to offer OVA1 services through its own labs in the remaining 11 states, until ASPiRA LABS has obtained the state approvals required to provide those services. Quest will receive a fee for collection and logistic support services it provides . Per the terms of the agreement, we will not offer to existing or future Quest Diagnostics customers CA 125 - II or other tests that Quest Diagnostics offers.

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 201 4 , virtually all of our product revenue was generated through Quest Diagnostics . In 2015, revenue will be generated through Quest Diagnostics and ASPiRA LABS. Outside the United States, laboratories may become customers, either directly with us or via distribution rel ationships established between us and authorized distributors. In 201 5 , we plan to begin to actively seek out distributors/partners outside the United States for an anticipated 201 6 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 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 and other gynecologic diseases .

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 IVDMIA 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 endpoint s. We plan to develop new IVDMIA 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 partner ships 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 solu tions 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 disease s 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 (e .g. , 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.

R&D- S ponsored I nitiatives to S upport M arket D evelopment 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 presurgical triage and evaluation of adnexal masses. The first is a major clinical study of OVA1, focused on its performance in the predominantly pre-menopausal non- g ynecologic o ncologist patient population. The study, called OVA500, was published in the February 2013 edition of *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 a dditional follow-on manuscripts were published in peer-reviewed publication s 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 p rincipal i nvestigators in the form of materials, testing services, and scientific consulting. As a part of this program, 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 e xten d our ovarian cancer franchise beyond OVA1 , enabled by several factors:

- We completed development and validation of a product improvement to OVA1 , known as OVA2, with submission of a FDA 510(k) clearance application o n March 6, 2015 ;

- The collection of clinical samples from prospectively enrolled adnexal surgery patients enables further biomarker and bio-analytical research, both in detection of ovarian cancer and also markers and risk factors for other gynecologic diseases which present with similar signs and symptoms;
- Vermillion possesses a large and growing portfolio of intellectual property, generated through collaborative research and licensing;
- T he acquisition of Correlogic ’s assets in 2011 br ought 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 ;
- Clinical collaborations such as the independent clinical research program mentioned above typically include licensing options when valuable intellectual property or product opportunities result; and
- 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 health markets to launch new products developed, licensed, co-marketed or acquired by any of these routes.

Our research and development expenses were $ 4,667 ,000 and $ 2,595 ,000 for the years ended December 31, 20 1 4 and 20 1 3 , respectively. The increase from the prior year was due primarily to a significant 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. We also operate a national CLIA certified clinical laboratory, ASPiRA LABS . Our sales representatives work to identify opportunities for educating general gynecologists and gynecologic oncologists on the benefits of OVA1 . In March 2015 , we announced that OVA1 was CE marked, a requirement for marketing the test in the European Union . In February 2015, Vermillion received ISO 13485:2003 certification for our quality management system from the British Standards Institution (BSI), one of the world's leading certification bodies. We plan to target markets outside of the United States once we have migrated OVA1 onto the Roche Cobas platform , which is available globally. In 201 5 , 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 201 6 .

Approximately 16,839 OVA1 tests were performed in 2014 compared to 17,004 in 2013 . Additionally, we estimate over 30% of U.S. gynecologic oncologists are supportive of 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.

In 2015, w e plan to continue to develop the market through exp erienced strategic account managers, market development specialists , customer account managers and medical scien ce liaisons . 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, the average g ynecologist 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 , the Medicare contractor that has jurisdiction over claims submitted by Quest Diagnostics for OVA1 , cover s and reimburses for OVA1 . This local coverage determination from Novitas Solutions essentially provide s national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. To the extent that testing is transitioned from Quest Diagnostics to ASPiRA LABS , we will assume responsibility for billing third-party payers for OVA1.

T he American Medical Association (“ AMA ”) Current Procedural Terminology (“ CPT ”) Panel approve d 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 Multianalyte Assays with Algorithmic Analyses (“ 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 expe ct OVA1 to be priced using the gap-f ill method . We will be engaged in that process in 201 5 for pricing effective January 1, 201 6 . 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.

New and innovative diagnostic tests often face reimbursement challenges that can affect adoption; the three key focus areas are coding, claims, and coverage or pay e r adoption.

Coding

- OVA1 is a new class of diagnostics , and therefore n o 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. A fter establishing OVA1 in the market, creating dem and 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 C PT c ode # 81503 was a critical step in our commercialization process.

- We believe Medicare currently reimburses OVA1 at $516 per test . Our test list price through ASPiRA LABS is $1,495 per test .

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 continue d 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 t o 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 ("ROMA"). ROMA combines two tumor markers and menopausal status into a numerical score using a publicly available algorithm. Th is test has the sam e intended use and precautions as OVA1. ROMA 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 .

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.

Intellectual Property Protection

Our intellectual property includes a portfolio of owned, co-owned or licensed patents and patent applications . As of December 31 , 201 4 , our clinical diagnostics patent portfolio included 16 issued United States patents, 14 pending United States patent applications, and numerous pending patent applications and issued patents outside the United States. These patents and patent applications fall into 30 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.

O ur existing research collaboration agreement with JHU extends through March 2016 . Collaboration costs under the JHU collaboration were $ 1,323 ,000 and $ 658 ,000 for the years ended December 3 1 , 201 4 and 201 3 , respectively . In addition, under the terms of our amended research collaboration agreement with JHU , 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 $5 7 , 5 00. 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 are 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. ASPiRA LABS is operated in material compliance with applicable federal and state laws and regulations relating to disposal of all laboratory specimens. We utilize 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 Federal 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 ") . 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 submitted a 510(k) clearance application to the FDA for our second-generation biomarker panel in early March 2015 with the goal of launching in the second half of 2015 . Pursuant to the 510(k) clearance process, the FDA may request additional information, and could require additional clinical evidence or analysis that may result in delays to this launch projection. In addition, one possible outcome of the 510(k) process is a finding that the product is "not substantially equivalent." Such a finding could require re-submission as a *de novo* 510(k) or PMA, resulting in serious delays and risks to commercialization. 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 generally conducts 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 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 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 ensure 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 ensure 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.

ASPiRA LABS and 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.

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 sta te 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 require s 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 . Failure to comply with our post-marketing study requirements may lead to enforcement actions by the FDA, including seizure of our product, injunction, prosecution and/or civil money penalties .

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. Medical device laws and regulations are 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 . Each country also maintains its own regulatory review process, tariff regulations, duties and tax requirements, product standards, and labeling requirements. In March 201 5 , OVA1 was CE marked, a requirement for marketing the test in the European Union. In February 2015 , Vermillion also received ISO 13485:2003 certification for our quality management system from the British Standards Institution (BSI), one of the world's leading certification bodies.

Employees

As of December 31, 201 4 , we had 31 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 . We will disclose on our website any waivers of, or amendments to, our Code of Ethics.

Corporate Information

We were originally incorporated in 1993, and we had our initial public offering in 2000. Our executive offices are located at 12117 Bee Caves Road, Building Three, Suite 100, Austin, Texas 787 38 , and our telephone number is (512) 519-0400. We maintain a website at www.vermillion.com and www.aspiralab.com where general information about us is available.

Information About Us

We file annual reports, quarterly reports, current reports, proxy statements, and other information with 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 , that contains reports, 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, 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 T hree , Suite 100
Austin, TX 78738

The information contained on our website s 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

Investing in our securities involves a high degree of risk. 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 . " If any of the following risks materializes, our business, financial condition , results of operations and growth prospects could be materially adversely affected, and the value of an investment in our common stock may decline significantly. The risks and uncertainties describe d 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 , results of operations and growth prospects

Risks Related to Our Business

If we are unable to increase the volume of OVA1 sales, our business , results of operations and financial condition w ill 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 2015 and the foreseeable future . Our losses have resulted principally from costs incurred in research and development, sales and marketing, and general and administrative costs.

All of our revenues have historically been generated from sales of OVA1 tests performed by Quest Diagnostics. Under our March 2015 agreement with Quest Diagnostics , OVA1 testing in the United States will be transitioned from Quest Diagnostics to ASPiRA LABS. Whether OVA1 testing is performed by Quest Diagnostics or us, if we are unable to increase the volume of OVA1 sales, our consolidated results of operations and financial condition would be adversely affected.

Virtually a ll of our revenue was derived from Quest Diagnostics during 201 4 , and there is no guarantee that we will be able to successfully market our test through additional channels , including ASPiRA LABS , in the future .

Virtually all of our revenue during 2014 was derived through our 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. On March 11, 2015, we entered into a new agreement with Quest Diagnostics pursuant to which, Quest Diagnostics has agreed to transition OVA1 testing services for its customers to ASPiRA LABS. After such testing services have been transitioned to ASPiRA LABS, we will still depend on Quest Diagnostics for blood draw and logistics for a significant portion of our specimens. There is no guarantee that Quest Diagnostics will perform as expected, or provide a sufficient volume of OVA1 test samples to support our business. Due in part to this uncertainty, 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 financial condition . Delays in the receipt of patient samples could result in delayed product revenues, reduction in revenues and in substantial additional costs.

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 .

Virtually a l l of our product revenue in 2014 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. CMS is in the process of developing payment codes and reimbursement rates under Medicare for certain next generation sequencing tests which may include certain MAAA, such as our OVA1 test. These new payment codes and rates are expected by January 1, 2016 , but there is no guarantee that CMS will issue them at that time, that the codes will cover the OVA1 test or that the payment rate will be comparable to current Medicare reimbursement levels for the test. Such uncertainty could create payment uncertainty from other payers as well. 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. In addition, there is no guarantee that our third-party payer experience will be similar to that of Quest Diagnostics.

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. If we are unable to obtain additional capital, we may not be able to continue our sales and marketing , research and development or other operations on the scope or scale of our current activity.

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 201 4 , all of our product revenue was generated in the United States. In 201 5 , 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 201 6 . 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 establish operations in countries outside of the United States, we may be subject to political, economic and other conditions affecting these countries that could result in increased operating expenses and regulation.

If we are able to execute on our plan to establish a market for OVA1 outside the United States, there are risks inherent in conducting business internationally, including the following:

- d ata privacy laws that may apply to the transmission of any clients' and employees' data to the United States;
- i mport/export sanctions and restrictions;
- c ompliance with applicable anti-corruption laws;
- d ifficulties in managing international distributors;
- a ccounting, tax and legal complexities arising from international operations;
- p otential difficulties in transferring funds generated overseas to the United States in a tax efficient manner; and
- p olitical and economic instability , including recent recessionary trends.

If we are able to establish operations in countries outside of the United States, changes in foreign exchange rates may adversely affect our revenue and net income.

If we are able to successfully commercialize OVA1 outside the United States, we expect that revenue and expense from our foreign operations will typically be denominated in local currencies, thereby creating exposure to changes in exchange rates. Revenue and profit generated by any international operations will increase or decrease as a result of changes in foreign currency exchange rates. Adverse changes to foreign exchange rates could decrease the value of revenue we receive from our contemplated international operations and have a material adverse impact on our business, results of operations and financial condition.

If we fail to continue to develop our existing technologies, we may not be able to successfully foster adoption of our products and services .

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 our existing 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.

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. In addition, development of products combining biomarkers with imaging, patient risk factors or other risk indicators carry higher than average risks due to technical, clinical and regulatory uncertainties. While we have published proof of concept on combining OVA1 and imaging, for example, our ability to develop, verify and validate an algorithm that generalizes to routine testing populations cannot be guaranteed. If successful, the regulatory pathway and clearance/approval process may require extensive discussion with applicable authorities and possibly, medical panels or other oversight mechanisms. These pose considerable risk in projecting launch dates, requirements for clinical evidence and eventual pricing and return on investment. Although we are engaging important stakeholders representing gynecologic oncology, benign gynecology, patient advocacy, women's health research, reimbursement and others , success, timelines and value will be uncertain and require active management at all stages of innovation and development.

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 U . S . 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 test 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 w ill be adversely affected. Additionally, in September 2011 , Fujirebio Diagnostics received FDA clearance for its ROMA test. ROMA 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 , and our revenues could be materially and adversely affected if the ROMA test is successfully commercialized. In addition, competitors, such as Becton Dickinson, ArrayIt Corporation, and Abbott Lab oratories 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.

Our diagnostic tests are subject to ongoing regulation by the FDA ; 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. In connection with the clearance of OVA1 we agreed to conduct certain post-market surveillance studies to further analyze performance of OVA1 in pre- and post-menopausal women. Failure to comply with our post-marketing study requirements may lead to enforcement actions by the FDA, including seizure of our product, injunction, prosecution and/or civil money penalties, which may harm our business , results of operations and financial condition.

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 Federal 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. 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 a *de novo* 510(k), 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.

I f we or our suppliers fail to comply with FDA requirements for production, marketing and post - market 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 QSR requirements , 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.

Effective December 2014, o ne of the five immunoassay component kits that are used in OVA1 ceased to be supported on the instrument as the manufacturer transitioned to a newer platform. While we have not experienced and do not anticipate disruption of ongoing operations, failure of the manufacturer to provide extended service or support might harm our business. W e 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 require a 510(k) clearance from the FDA. No assurances can be made that the FDA will clear our 510(k) submission , which was made in March 2015 . Any resulting disruption to our supply of OVA1 may adversely affect our business, financial condition and results of operations.

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 JHU and M.D. Anderson. 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 , and the attention of our management may be diverted from our business . We may not be successful in asserting our proprietary rights , 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 its 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 . I f 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.

F uture 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 o f their intellectual property rights. In addition, we may bring claims against third parties for infringement o f 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 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. I f 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 % of the price for which such manufacturer sells its medical devices. The PPACA also mandated a reduction in payments of 1.75% for the years 2011 through 2015 for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule. This adjustment was in addition to a productivity adjustment to the Clinical Laboratory Fee Schedule. In April 2014, President Barack Obama signed the Protecting Access to Medicare Act of 2014, which halted certain reductions in payment mandated by the PPACA as well as certain CMS policies, and will instead establish a market-based reimbursement system for clinical laboratories beginning in 2017 and require reporting of certain private payer reimbursement data by laboratories beginning in 2016. CMS also issued various regulations and guidance generally effective January 1, 2014 that limited reimbursement for clinical laboratory tests as a general matter, but permitted the continued ability for CMS to pay for MAAAs in certain circumstances. In addition to these changes, 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 the 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.

W e 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.

The success of ASPiRA LABS depends, in part, on our ability to generate sufficient demand for its services to cover the laboratory's operating costs, and there is no assurance that we will be able to do so successfully.

The launch of our new clinical laboratory, ASPiRA LABS, involves significant costs to us, including the costs of laboratory equipment and facilities, outside consulting fees for branding and other services and other general and administrative expenses. We expect to continue to incur significant costs to operate ASPiRA LABS in the future, such as salaries and related expenses for personnel, regulatory compliance costs and ongoing costs of outsourced billing services. There is no guarantee that we will be able to generate a sufficient volume of patients to access the laboratory and utilize its offerings to cover the fixed and ongoing costs of ASPiRA LABS.

R evenue from ASPiRA LABS has been minimal to date , and there is no guarantee that we be able to generate sufficient revenue in the future to offset our costs . Our inability to successfully develop sufficient demand for the diagnostic tests processed by the laboratory could delay or prevent ASPiRA LABS from generating material revenue, and we may not achieve revenues or profitability from ASPiRA LABS in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our ASPiRA LABS operations or we may be unable to expand our offerings at ASPiRA LABS beyond ovarian cancer to other gynecologic conditions with high unmet need as we intend .

The launch of ASPiRA LABS requires us to comply with numerous laws and regulations, which is expensive and time-consuming and could adversely affect our business, financial condition and results of operations, and any failure to comply could result in exposure to substantial penalties and other harm to our business.

In June 2014, we launched a clinical laboratory, ASPiRA LABS. Clinical laboratories that perform tests on human subjects in the United States for the purpose of providing information for the diagnosis, prevention or treatment of disease must be certified under CLIA and licensed under applicable state laboratory laws. CLIA regulates the quality of clinical laboratory testing by requiring laboratories to comply with various technical, operational, personnel and quality requirements intended to ensure that the services provided are accurate, reliable and timely. State laws may require that additional quality standards be met and that detailed review of scientific validations and technical procedures for tests occur.

We received our temporary CLIA Certificate of Registration effective February 18, 2014 and , as of the date of this Annual Report on Form 10-K, we are in the process of obtaining a full Certificate of Accreditation and state laboratory licensure from certain states. We are subject to periodic surveys and inspections to maintain our CLIA certification, and such certification is also required to obtain payment from Medicare, Medicaid and certain other third-party payers. Failure to comply with CLIA or state law requirements may result in the imposition of corrective action or the denial, suspension or revocation of our CLIA certification or state licenses. If our CLIA certification or state licenses are denied, suspended or revoked or our right to bill the Medicare and Medicaid programs or other third-party payers is suspended, we would no longer be able to sell our tests, which would adversely affect our business, financial condition and results of operations.

In addition, no assurance can be given that ASPiRA LABS ' suppliers or commercial partners will remain in compliance with applicable CLIA and other federal or state regulatory requirements for laboratory operations and testing. ASPiRA LABS' facilities and procedures and those of ASPiRA LABS' suppliers and commercial partners are subject to ongoing regulation, including periodic inspection by regulatory and other government authorities. Possible regulatory actions for non-compliance could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of ASPiRA LABS' products, and criminal prosecution.

Our clinical laboratory business is also subject to regulation at both the federal and state level in the United States, as well as regulation in other jurisdictions outside of the United States, including:

- Medicare and Medicaid coverage, coding and payment regulations applicable to clinical laboratories;
- the Federal Anti Kickback Statute and state anti-kickback prohibitions;
- the federal physician self-referral prohibition, commonly known as the Stark Law, and state self-referral prohibitions;

- the Medicare civil monetary penalty and exclusion requirements;

- the Federal False Claims Act civil and criminal penalties and state equivalents; and

- the Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH");

Many of these laws and regulations prohibit a laboratory from making payments or furnishing other benefits to influence the referral of tests (by physicians or others) that are billed to Medicare, Medicaid or certain other federal or state healthcare programs. The penalties for violation of these laws and regulations may include monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Several states have similar laws that may apply even in the absence of government payers. HIPAA and HITECH and similar state laws seek to protect the privacy and security of individually identifiable health information, and penalties for violations of these laws may include required reporting of breaches, monetary fines and criminal or civil penalties.

While we seek to conduct our business in compliance with all applicable laws and develop compliance policies to address risk as appropriate, many of the laws and regulations applicable to us are vague or indefinite and have not been interpreted by governmental authorities or the courts. These laws or regulations also could in the future be interpreted or applied by governmental authorities or the courts in a manner that could require us to change our operations.

Any action brought against us for violation of these or other laws or regulations (including actions brought by private *qui tam* "whistleblower" plaintiffs), even if successfully defended, could divert management's attention from our business, damage our reputation, limit our ability to provide services, decrease demand for our services and cause us to incur significant expenses for legal fees and damages. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal penalties, fines, recoupment of funds received by us , exclusion from participation in federal or state healthcare programs, and the loss of various licenses, certificates and authorizations necessary to operate our business. We also could potentially incur additional liabilities from third-party claims. If any of the foregoing were to occur, it could have a material adverse effect on our business, financial condition and results of operations.

In the future, we plan to develop and perform LDTs at ASPiRA LABS. If the FDA proceeds with its plans to actively regulate LDTs , we may need to obtain a 510(k) clearance or PMA for our future LDTs, and there is no guarantee that we would ever procure the needed FDA clearance or approval.

We intend to develop and perform LDTs at ASPiRA LABS. The FDA has historically exercised enforcement discretion and not required approvals or clearances for LDTs. However in July 2014, the FDA notified Congress of its intent to issue two draft guidance documents regarding oversight of LDTs. If the FDA were to issue and finalize those draft guidances, depending on the level of risk of the test, a laboratory might have to submit a PMA as early as 12 months after the guidance is finalized, could be exempt from pre-market review altogether, or have to submit a PMA or 510(k) sometime after 12 months after the guidance is finalized.

The FDA's proposed framework in the notification to Congress also outlines post-market controls including registration and listing or FDA notification, compliance with the QSR requirements, and adverse event reporting that will be required of all LDTs except for those for forensic (law enforcement) use and transplantation. In addition, the FDA has indicated that if a laboratory runs a test that has received a 510 (k) clearance in a manner that is different from the instructions for use, then the FDA will consider that changed test to be a LDT.

Even before the FDA finalizes such guidance, the FDA may assert that a test that we believe to be an LDT is not an LDT and could require us to seek clearance or approval to offer such tests for clinical use. If the FDA pre-market review or approval is required for any of the future LDTs we may develop, we may be forced to stop selling our tests or be required to modify claims or make such other changes while we work to obtain FDA clearance or approval. Our business would be negatively affected until such review is completed and clearance to market or approval is obtained.

If pre-market review is required by the FDA or if we decide to voluntarily pursue FDA pre-market review of our future LDTs, there can be no assurance that any tests we develop in the future will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations for those tests would increase the cost of conducting our business and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

Risks Related to Owning O ur 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 stock holders ' ability to obtain liquidity in their shares. The issuance of common stock by us in May 2013 and subsequent warrant exercise in December 2013 , and the issuance of common stock by us in December 2014 , involved a significant issuance of stock to a limited number of investors, significantly increasing the concentration of our share ownership in a few holders.

According to information provided on Schedule 13D, four persons beneficially owned approximately 58% of our outstanding shares of common stock as of March 27 , 2015, and under a May 2013 stockholders agreement, two of these persons have certain rights to designate a director to be nominated by us to serve on the Board of Directors . As a result, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock.

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.

Certain provisions of our certificate of incorporation and bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us, even if a change of control might be deemed beneficial to our stockholders. Such provisions could limit the price that certain investors might be willing to pay in the future for our securities. Our certificate of incorporation eliminates the right of stockholders to call special meetings of stockholders or to act by written consent without a meeting, and our bylaws require advance notice for stockholder proposals and director nominations, which may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders. Our certificate of incorporation also authorizes undesignated preferred stock, which makes it possible for our board of directors, without stockholder approval, to issue preferred stock with voting or other rights or preferences

that could adversely affect the voting power of holders of common stock. In addition, the likelihood that the holders of preferred stock will receive dividend payments and payments upon liquidation could have the effect of delaying, deferring or preventing a change in control .

In connection with our private placement offering of common stock and warrants on May 13, 2013, we entered into a stockholders agreement which , among other things, includes agreements limiting our ability to effect a change in control without the consent of at least one of the two primary investors in that offering. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of us. The amendment of any of the provisions of either our certificate of incorporation or bylaws described in the preceding paragraph would require not only approval by our board of directors and the affirmative vote of at least 66 2/3% of our then outstanding voting securities, but also the consent of at least one of the two primary investors in the May 2013 offering . We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company. These provisions could make a third-party acquisition of the Company difficult and limit the price that investors might be willing to pay in the future for shares of our common stock .

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, 201 4 , we had 43,11 5 , 790 shares of our common stock outstanding and 737,434 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 1, 711,046 shares of our common stock that were subject to outstanding options. In addition, as of December 31, 2014 , warrants to purchase 4,629 ,000 shares of our commo n stock were outstanding . These warrants are exercisable at the election of the holders thereof at an average exercise price of $ 1. 96 per share.

The exercise of all or a portion of our outstandi ng 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.

If an increase to the 2010 Stock Incentive Plan is not approved by stockholders, the limited number of shares we could issue may impact our ability to attract, retain and motivate key personnel .

We have a limited number of shares available under the Vermillion Inc. Amended and Restated 2010 Stock Incentive Plan (the “2010 Plan”). We plan to seek stockholder approval of an increase in the number of shares available for issuance under the 2010 Plan, but there can be no assurances that such increase will be approved. We have historically used stock options as a significant component of our employee compensation program in order to align employees’ interests with the interests of our stockholders, encourage employee retention, and provide competitive compensation packages. If we are unable to increase the number of shares available under the 2010 Plan, our ability to offer attractive equity incentive awards in the future may be limited or nonexistent and may make it more difficult for us to attract, retain and motivate key personnel.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal facility is located in Austin, Texas, and the ASPiRA LABS facility is located in Georgetown, Texas. The following chart indicates the facilit ies that we lease, the location and size of each facility and its designated use. We believe that these facilities are suitable and adequate for our current needs.

Location	Approximate Square Feet	Primary Functions	Lease Expiration Date
Austin, Texas	7,270 sq. ft.	Research and development, clinical and regulatory, marketing, sales and administrative offices	May 31, 201 6
Georgetown, Texas	877 sq. ft .	Diagnostic laboratory	June 30, 2015

ITEM 3. LEGAL PROCEEDINGS

F rom 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. W e 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 is traded on t he N ASDAQ Capital Market under the symbol "VRML."

On March 26 , 201 5 , there were 89 registered holders of record of our common stock. The closing price of our common stock on March 26 , 2015 was $ 1.85 .

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.

	2014		2013	
	High	Low	High	Low
First Quarter	$ 3.83	$ 2.33	$ 3.10	$ 1.97
Second Quarter	3.34	2.42	3.24	2.11
Third Quarter	2.70	1.50	4.07	1.03
Fourth Quarter	2.20	1.20	1.48	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

On December 23, 2014 , we completed a private placement of unregistered shares of our common stock. We sold 6,944,445 shares of our common stock at a price of $1.44 per share , being the closing price per share of Vermillion common stock on the NASDAQ Capital Market on December 18, 2014, for an aggregate purchase price of $10.0 million. We also issued warrants to purchase 4,166,659 shares of common stock at a price of $0.125 per warrant share in the private placement, for an aggregate purchase price of $0.5 million. The proceeds of the private placement were $10,521,000 (net proceeds of approximately $10,281,000 after deducting offering expenses). The warrants are exercisable, beginning on June 23, 2015, for 4,166,659 shares of Vermillion common stock at $2.00 per share and expire on December 23, 2017. The Company intends to use the net proceeds from the private placement for working capital and general corporate purposes.

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 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, 201 4 , options to purchase 57,900 shares of our common stock remain ed ou tstanding 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 , 6 22,983 shares of our common stock under the 2010 Plan, subject to adjustment as provided in the 2010 Plan. At December 31, 201 4 , options to purchase 1, 653,146 shares of common stock remain ed outstanding under the 201 0 Plan.

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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, 201 4 , were as follows:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Shares Reflected in First Column)
Equity compensation plans approved by security holders	1,711,046 (1)	$ 2.62 (2)	737,434 (3)
Equity compensation plans not approved by security holders	-	-	-
Total	1,711,046		737,434

(1) Includes outstanding stock options for 57,900 shares of our common stock under the 2000 Plan and 1,653,146 shares of our common stock under the 2010 Plan.

(2) Includes the weighted average stock price for outstanding stock options of $4.21 under the 2000 Plan and $2.56 for the 2010 Plan.

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

Performance Graph

Pursuant to the accompanying instructions, the information called for by Item 201(e) of Regulation S-K is not required.

ITEM 6. SELECTED FINANCIAL DATA

Per Item 301(c) of Regulation S-K, the information called for by Item 6 of Form 10-K is not required.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CON DITION AND RESULTS OF OPERATION S

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 and bio-analytical solutions that help physicians diagnose, treat and improve outcomes for women. Our tests are intended to detect, characterize and stage disease, and to help guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, or to assist in monitoring response to 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 for gynecologic disease , 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.

Our lead product, OVA1, is a blood test designed to identify women who are at high risk of having a malignant ovarian tumor prior to surgery. The FDA cleared OVA1 in September 2009 , and we commercially launched OVA1 in March 2010. We have completed development and validation work on a second-generation biomarker panel intended to maintain our product's high sensitivity while improving specificity. We submitted our 510(k) clearance application to the FDA in March 2015, with the goal of launching in the second half of 2015. The product will use the Roche Cobas platform.

OVA1 addresses a clear clinical need, namely the presurgical 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 presurgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary software cleared as part of the OVA1 510(k) to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary testing, surgery and delayed diagnosis.

Strategy:

We are focused on the execution of four 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 by expanding our direct market reach beyond our current commercial agreement with Quest Diagnostics and taking the lead in payer coverage and commercialization of OVA1. This strategy includes the launch of a CLIA certified clinical laboratory, ASPiRA LABS, in June 2014;

- Improving OVA1 performance by seeking FDA clearance of a potentially better performing biomarker panel while migrating OVA1 to a global testing platform, thus allowing for better domestic market penetration and international expansion;

- Building an expanded patient base by launching a next generation multi-marker ovarian cancer test to monitor patients at risk for ovarian cancer ; and

- Expanding our product offerings by adding additional gynecologic bio-analytic solutions involving biomarkers, other modalities (e.g. , imaging), clinical risk factors and patient data to aid diagnosis and risk stratification of women presenting with a pelvic mass disease.

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

In June 2014, Vermillion launched ASPiRA LABS, a CLIA certified national laboratory based near Austin, Texas, which specializes in applying biomarker-based technologies and offers OVA1 to address critical needs in the management of gynecologic cancers. ASPiRA LABS provides expert diagnostic processing and results using a state-of-the-art biomarker-based diagnostic algorithm to inform clinical decision making and advance personalized treatment plans. In addition, ASPiRA LABS seeks to serve as an educational and resource hub for healthcare professionals and women facing surgery for potentially-cancerous ovarian masses and

related gynecologic conditions. The lab currently processes our OVA1 test, and we expect the lab to process our second-generation panel in the future. We plan to expand the testing provided by the lab to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPiRA LABS. ASPiRA LABS currently holds a CLIA Certificate of Registration and a state laboratory license in California and Rhode Island. ASPiRA LABS is in the process of obtaining state licensure in New York, Florida, Maryland and Pennsylvania. The CMS issued a provider number to ASPiRA LABS on March 5, 2015.

We terminated our Strategic Alliance Agreement with Quest Diagnostics in August 2013. Prior to the termination of the Strategic Alliance Agreement, Quest Diagnostics had the right to be the exclusive clinical reference laboratory marketplace provider of OVA1 tests in its exclusive territory, which included the United States, Mexico, the United Kingdom and India. As part of the termination, we agreed that Quest Diagnostics could continue to make OVA1 available to healthcare providers under legacy financial terms following the termination while negotiating in good faith towards an alternative business structure. Quest Diagnostics disputed the effectiveness of such termination.

As a result of ongoing negotiations, on March 11, 2015, we reached a settlement agreement with Quest Diagnostics that terminated all disputes related to our prior strategic alliance and loan agreements. We also entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, Vermillion's wholly-owned subsidiary, ASPiRA LABS , will begin to offer OVA1 testing to Quest Diagnostics customers. We expect Quest Diagnostics to transfer all OVA1 U.S. testing services to ASPiRA LABS , starting with 39 states this year, while continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing for a period of two years from the date of the agreement. Pursuant to the agreement, Quest Diagnostics will also continue to offer OVA1 services through its own labs in the remaining 11 states , until ASPiRA LABS has obtained the state approvals required to provide those services. Quest will receive a fee for collection and logistic support services it provides . Per the terms of the agreement, we will not offer to existing or future Quest Diagnostics customers CA 125 - II or other tests that Quest Diagnostics offers.

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 2015 for pricing effective January 1, 2016 . 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 ("GAAP") . 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 . The Company derives product revenues from sales of OVA1 through Quest Diagnostics and ASPiRA LABS. 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.

As the Company has not established sufficient payment history with the ins urance companies or private pay e rs for the tests performed at ASPiRA LABS, payment is not fixed or determinable and collectability is not reasonably assured, and we will defer recognizing revenues until those criteria are met, which typically coincides with the collection of cash. Once we establish a reliable payment history, we plan to return to normal accrual revenue recognition based on our criteria discussed above.

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 ed for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest Diagnostics receive d upon commercialization of an approved diagnostic test as we d id

not have a sufficient history of product sales that provided a reasonable basis for estimating future product sales. Through December 31, 2014, w e recognize d license revenue on a straight-line basis over the original remaining period of Quest Diagnostics' sales exclusivity ending in September 2015 . The disputed exclusivity was formally terminated with Quest Diagnostic s as part of the March 11 , 2015 agreement , and thus the remaining balance of deferred license revenue totaling $315,518 will be recognized in the first quarter of 2015 .

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.

Stock-Based Compensation

We record the fair value of non-cash stock-based compensation costs for stock options and stock purchase rights related to the 2010 Plan. We estimate t he 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 t he 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 August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update 2014-15, "Presentation of Financial Statements – Going Concern," (ASU 2014-15). ASU 2014-15 provides guidance with regard to

management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 clarified that management should perform its evaluation whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The accounting standard is effective for annual periods ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted. Upon adoption , management will evaluate the Company's ability to continue as a going concern based on this guidance.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period," (ASU 2014-12). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in ASU 2014-12 are effective for annual periods and interim periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of this standard is not expected to have a material effect on our financial statements.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers," (ASU 2014-09), which creates a new Topic, Accounting Standards Codification Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The accounting standard is effective for annual and interim periods beginning after December 15, 2016 , using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical ex p edients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption . Early adoption is not permitted. We are currently evaluating the impact and the method of adopting this standard .

Results of Operations – Year Ended December 31, 201 4 as compared to Year Ended December 31, 201 3

The selected summary financial and operating data of Vermillion for the years ended December 31, 201 4 and 201 3 were as follows:

	Year Ended December 31,		Increase (Decrease)	
(dollars in thousands)	2014	2013	Amount	%
Revenue:				
Product	$ 2,067	$ 2,112	$ (45)	(2)
License	454	454	-	-
Total revenue	2,521	2,566	(45)	(2)
Cost of revenue:				
Product	1,230	170	1,060	624
Gross profit	1,291	2,396	(1,105)	(46)
Operating expenses:				
Research and development	4,667	2,595	2,072	80
Sales and marketing	9,893	4,480	5,413	121
General and administrative	5,942	4,184	1,758	42
Total operating expenses	20,502	11,259	9,243	82
Loss from operations	(19,211)	(8,863)	(10,348)	117
Interest income	40	23	17	74
Other income (expense), net	(38)	21	(59)	(281)
Loss before income taxes	(19,209)	(8,819)	(10,390)	118
Income tax benefit (expense)	-	-	-	-
Net loss	$ (19,209)	$ (8,819)	$ (10,390)	118

Product Revenue . Product revenue was $ 2,067 ,000 for the year ended December 31, 201 4 compared to $ 2,112 ,000 for the same period in 201 3 . We recognized product revenue for the year ended December 31, 201 4 for the sale of OVA1 through Quest Diagnostics. Our total OVA1 volume was 16,839 for 2014. This was comprised of 16,427 tests performed by Quest Diagnostics and 412 OVA1 tests performed by ASPiRA LABS . There were approximately 17,004 OVA1 tests performed during the year ended December 31, 201 3 . Product revenue for ASPiRA LABS tests are recognized on the cash basis and thus 2014 revenue was insignificant.

We recognized $ 1,2 27 ,000 of deferred revenue in 201 4 upon receipt of an annual royalty report from Quest Diagnostics compared to $ 1,262 ,000 for 201 3 . The 201 4 annual royalty report of $ 1,2 27 ,000 was based upon 16, 563 OVA1 tests reported by Quest Diagnostics as resolved in 201 4 , 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, 201 4 . By comparison, the 201 3 annual royalty report of $ 1,262 ,000 was based upon 16,745 OVA1 tests reported by Quest Diagnostics as resolved in 201 3 . The royalty report revenue is incremental to the fixed $50 per test recognized for each OVA1 performed during the year. Based upon the new agreement with Quest Diagnostics effective March 11 , 2015, we expect to recognize revenue for OVA1 test s performed by Quest Diagnostics in the period in which the test is performed.

Cost of Revenue. Cost of product revenue for the year ended December 31, 2014 increased $1,060,000 compared to the same period in 2013. Cost of product revenue for the year ended December 31, 2014 primarily consists of costs of ASPiRA LABS incurred after the lab began accepting test samples on June 23, 2014 and includes approximately $250,000 of non-recurring lab start-up costs.

We expect cost of revenue to increase in future periods as sample throughput increases and as we complete the ASPiRA LABS buildout.

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. Rese arch and development expenses in creased by $ 2,072 ,000, or 80 %, for the year ended December 31, 201 4 com pared to the same period in 201 3 . This increase was primarily due to increased costs during 2014 associated with our collaboration with JHU , as we made agreed upon payments to JHU for its assistance with advancing our platform migration and developing our next-generation diagnostic test. In addition, we increased research and development headcount compared to the same period in 2013.

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 field sales force , the subject matter experts responsible for market development. Sales and marketing expenses in creased by $ 5,413 ,000, or 121 %, for the year ended December 31, 201 4 com pared to the same period in 201 3. The increase was primarily due to increased personnel and personnel-related expenses from our sales force expansion in April 2014 as well as costs incurred in the establishment and branding of ASPiRA LABS in 2014 compared to the same period in 2013. We also incurred a one-time $211,000 cost of severance for our former Senior Vice President, Sales and Marketing and expenses for health economic and outcomes studies during the year ended December 31 , 2014. There were no such expenses in the comparable period in 2013.

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 oth er infrastructure expenses . General and administrative expenses in creased by $ 1,758 ,000, or 42 %, for the year ended December 31, 201 4 com pared to the same period in 201 3 . The change was primarily due to a one-time $416,000 cost of severance for our former President and Chief Executive Officer and $552,000 of pre-opening costs incurred for ASPiRA LABS prior to June 23, 2014 (the o pening date for ASPiRA LABS). In addition, we incurred significant non-recurring consulting fees as well as offering costs of $198,000 in excess of the proceeds received related to our at-the-market equity offering .

Liquidity and Capital Resources

On December 2 3, 201 4 , the Company completed a private placement pursuant to which certain investors purchased 6,944,445 shares of Vermillion common stock at a price of $ 1.4 4 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 $ 10,521,000 (net proceeds of approximately $ 10,281 ,000 after deducting offering expenses incurred through December 31, 2014). The warrants are exercisable , beginning on June 23, 2015, for 4,166,659 shares of Vermillion common stock at $ 2 . 00 per share and expire on December 23, 2017 .

We have incurred significant net losses and negative cash flows from operations since inception. At December 31, 201 4 , we had an accumulated deficit of $ 3 51,473, 000 and stockholders' equity of $ 19,255 ,000. On December 31, 201 4 , we had $2 2 , 965 ,000 of cash and cash equivalents and $ 4,919 ,000 of current liabilities. The Company expects to incur a net loss in 2015 and the foreseeable future.

There can be no assurance that we will achieve or sustain profitability or positive cash flow from operations. In addition, while we expect to grow revenue with the addition of ASPiRA LABS, there is no assurance of our ability to generate substantial revenues and cash flows from ASPiRA LABS ’ operations. We expect cash from our products to be our only material, recurring source of cash in 2015.

Our management believes that our current working capital as of December 31, 2014 will be sufficient to meet the Company’s working capital needs for at least the next twelve months. However, our management also believes that the successful achievement of our business objectives will require additional financing. We expect to raise capital through a variety of sources, which may include the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and public or private debt.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants and potential dilution to stockholders. If we obtain additional funds through arrangements with collaborators or strategic partners, we may be required to relinquish our rights to certain technologies or products that we might otherwise seek to retain. Additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may not be able to continue our sales and marketing, research and development, or other operations on the scope or scale of current activity , and that could have a material adverse effect on the business , financial condition and results of operations .

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;
- the successful launch of OVA2 in the second half of 2015; and
- the insurance payer community's acceptance of and reimbursement for OVA1 .

Cash and cash equivalents as of December 31, 201 4 and December 31, 20 1 3 were $ 22,965 ,000 and $ 29,504 ,000, respectively. At December 31, 201 4 and 201 3 , working capital was $ 18,747 ,000 and $ 26,691 ,000 , respectively .

Net cash used in operating activities was $ 16,808 ,000 for the year ended December 31, 201 4 , resulting primarily from $ 19,209 ,000 net loss incurred as adjusted for non-cash license revenues of $454,000, partially offset by $ 1,149 ,000 of stock-based compensation expense. Net cash used in operating activities also included $ 1,543 ,000 of cash used from changes in operating assets and liabilities and primarily from increases in accounts payable and accrued liabilities .

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 investing activities was $258 ,000 for the year ended December 31, 2014 due to equipment and software purchases for ASPiRA LABS as well as computer purchases. 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 financing activities was $ 10,527 ,000 for the year ended December 31, 2014 due to receipt of $10,288 ,000 of net proceeds from the sale of common stock and $239,000 in proceeds from the exercise of stock options. 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 the sale of common stock and exercise of warrants as well as $644,000 in proceeds from the exercise of stock options.

Off-Balance Sheet Arrangements

As of December 31, 201 4 , 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, the information called for by Item 7A is not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, including consolidated balanc e sheets as of December 31, 20 1 4 and 20 1 3 , consolidated statements of operations for t he years ended December 31, 201 4 and 20 1 3 , consolidated statements of changes in stockholders' equity for the years ended December 31, 201 4 and 20 1 3 , consolidated statements of cash flows for t he years ended December 31, 201 4 and 20 1 3 and notes to our consolidated financial statements, together with a report thereon of our independent registered public accounting firm 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 S EC '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 Dec ember 31, 201 4 .

Based on that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of December 3 1, 201 4 , 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 o n 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, 201 4 . Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, entitled " Internal Control - Integrated Framework (2013) . "

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 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, 2014 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, 201 4 , 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, 201 4 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 Boar d of Directors, Committees and Corporate Governance," " Management " and "Section 16(a) Beneficial Ownership Reporting Compliance," of our proxy statement relating to our 20 1 5 Annual Meeting of Stockholders to be held in 20 1 5 (the " 20 1 5 Proxy Statement") is incorporated by reference.

Our code of ethics is applicable to all employees, including both our Chief Executive Officer , Principal Financial Officer and Controller . This code of ethics is publicly available on our website at 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 20 1 5 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 20 1 5 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 20 1 5 Proxy Statement is incorporated by reference.

ITEM 14. PRINCIPAL ACCOUNT ANT FEES AND SERVICES

The information appearing under the heading " Ratification of the Selection of the Independent Registered Public Account ing Firm for Vermillion " of the 20 1 5 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 the reon, 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 A nnual R eport on Form 10-K .

VERMILLION , INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 201 4 and 201 3 and the related consolidated statements of operations, 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 audit s .

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, 201 4 and 201 3 , 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 31 , 201 5

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

	December 31,	
	2014	**2013**
Assets		
Current assets:		
Cash and cash equivalents	$ 22,965	$ 29,504
Accounts receivable	167	373
Prepaid expenses and other current assets	534	372
Total current assets	23,666	30,249
Property and equipment, net	508	391
Total assets	$ 24,174	$ 30,640
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,123	$ 541
Accrued liabilities	2,201	1,283
Short-term debt	1,106	1,106
Deferred revenue	489	628
Total current liabilities	4,919	3,558
Non-current liabilities:		
Long-term deferred revenue	-	316
Total liabilities	4,919	3,874
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, 2014 and 2013	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized; 43,115,790 and 35,825,673 shares issued and outstanding at December 31, 2014 and 2013, respectively	43	36
Additional paid-in capital	370,685	358,994
Accumulated deficit	(351,473)	(332,264)
Total stockholders' equity	19,255	26,766
Total liabilities and stockholders' equity	$ 24,174	$ 30,640

See accompanying Notes to Consolidated Financial Statements

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

	Year Ended December 31,	
	2014	**2013**
Revenue:		
Product	$ 2,067	$ 2,112
License	454	454
Total revenue	2,521	2,566
Cost of revenue:		
Product	1,230	170
Gross profit	1,291	2,396
Operating expenses:		
Research and development [(1)]	4,667	2,595
Sales and marketing [(2)]	9,893	4,480
General and administrative [(3)]	5,942	4,184
Total operating expenses	20,502	11,259
Loss from operations	(19,211)	(8,863)
Interest income	40	23
Other income (expense), net	(38)	21
Loss before income taxes	(19,209)	(8,819)
Income tax benefit (expense)	-	-
Net loss	$ (19,209)	$ (8,819)
Net loss per share - basic and diluted	$ (0.53)	$ (0.42)
Weighted average common shares used to compute basic and diluted net loss per common share	36,082,414	20,926,336
Non-cash stock-based compensation expense included in operating expenses:		
(1) Research and development	$ 136	$ 76
(2) Sales and marketing	259	163
(3) General and administrative	776	637

See accompanying Notes to Consolidated Financial Statements

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

	Common Stock				
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2012	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
Balance at December 31, 2013	35,825,673	36	358,994	(332,264)	26,766
Net loss	-	-	-	(19,209)	(19,209)
Common stock and warrants issued in conjunction with private placement sale, net of issuance costs	6,944,445	7	10,281	-	10,288
Common stock offering - at-the-market (ATM)	48,473	-	-	-	-
Common stock issued in conjunction with exercise of stock options	178,699	-	239	-	239
Common stock issued for restricted stock awards	118,500	-	351	-	351
Warrants issued for services	-	-	22	-	22
Stock compensation charge	-	-	798	-	798
Balance at December 31, 2014	43,115,790	$ 43	$ 370,685	$ (351,473)	$ 19,255

See accompanying Notes to Consolidated Financial Statements

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

	Year Ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (19,209)	$ (8,819)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash license revenue	(454)	(454)
Depreciation and amortization	141	72
Stock-based compensation expense	1,149	842
Warrants issued for services	22	34
Changes in operating assets and liabilities:		
Increase (decrease) in accounts receivable	206	(236)
Increase in prepaid expenses and other current assets	(162)	(24)
Increase in accounts payable and accrued liabilities	1,500	225
(Decrease) increase in deferred revenue	(1)	136
Net cash used in operating activities	(16,808)	(8,224)
Net Cash flows from investing activities:		
Purchase of property and equipment	(258)	(321)
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants, net of issuance costs	10,288	11,751
Proceeds from exercise of common stock warrants	-	17,647
Proceeds from issuance of common stock from exercise of stock options	239	644
Net cash provided by financing activities	10,527	30,042
Net (decrease) increase in cash and cash equivalents	(6,539)	21,497
Cash and cash equivalents, beginning of year	29,504	8,007
Cash and cash equivalents, end of year	$ 22,965	$ 29,504

See accompanying 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 for gynecologic disease. In March 2010, the Company commercially launched OVA1™ ovarian tumor triage test ("OVA1"). The Company distributes OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics"), a related party (see Note 3) and through its wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, Inc ("ASPiRA"), which opened on June 23, 2014.

Liquidity

On December 23, 2014, the Company completed a private placement pursuant to which certain investors purchased 6,944,445 shares of Vermillion common stock at a price of $1.44 per share. The Company also issued warrants to purchase shares of Vermillion common stock at a price of $0.125 per warrant share in the private placement. The proceeds of the private placement were $10,521,000 (net proceeds of approximately $10,281,000 after deducting offering expenses incurred through December 31, 2014). The warrants are exercisable, beginning on June 23, 2015, for 4,166,659 shares of Vermillion common stock at $2.00 per share and expire on December 23, 2017.

The Company has incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of $351 million at December 31, 2014. The Company expects to incur a net loss in 2015 and the foreseeable future. The Company's management believes that successful achievement of the business objectives will require additional financing. The Company expects to raise capital through a variety of sources, which may include the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and/or public or private debt. However, additional funding may not be available when needed or on terms acceptable to the Company. If the Company is unable to obtain additional capital, it may not be able to continue sales and marketing, research and development, or other operations on the scope or scale of current activity and that could have a material adverse effect on the business, results of operations and financial condition.

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 as of the date of these financial statements will be sufficient to meet the Company's working capital needs for at least the next twelve months. Management expects cash from product sales to be the Company's only material, recurring source of cash in 2015.

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 the Company's consolidated financial statements include assumptions regarding variables used in calculating the fair value of the Company's 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 the Company 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, 2014 and 2013 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 and ASPiRA. 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.

As the Company has not established sufficient payment history with the insurance companies or private payors for the tests perfor med at ASPiRA, payment is not fixed or determinable and collectability is not reasonably assured, and it will not recogniz e revenue until those criteria are met, which typically coincides with the collection of cash. All costs incurred for tests performed at ASPiRA are expensed as incurred. Once the Company establishes a reliable payment history, it plans to return to normal accrual revenue recognition based on its criteria discussed above.

License Revenue: Under the terms of the secured line of credit with Quest Diagnostics, which was terminated on March 11, 2015, portions of the borrowed principal amounts were 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. The disputed exclusivity was formally terminated with Quest Diagnostics on March 11, 2015, and thus the remaining balance of deferred license revenue totaling $315,518 will be recognized as of that date.

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 the Company's 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. Such costs aggregated approximately $380,000 and $475,000 for the years ended December 31, 2014 and 2013, 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 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 Vermillion 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. Managements 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.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of shares of common stock 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 August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update 2014-15, "Presentation of Financial Statements – Going Concern," (ASU 2014-15). ASU 2014-15 provides guidance with regard to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 clarified that management should perform its evaluation whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The accounting standard is effective for annual periods ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted. Upon adoption management will evaluate the Company's ability to continue as a going concern based on this guidance.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period," (ASU 2014-12). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in ASU 2014-12 are effective for annual periods and interim periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of this standard is not expected to have a material effect on the Company's financial statements.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers," (ASU 2014-09), which creates a new Topic, Accounting Standards Codification Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The accounting standard is effective for annual and interim periods beginning after December 15, 2016 , using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption. Early adoption is not permitted. The Company is currently evaluating the impact and the method of adopting this standard .

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 the Company's 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 the Company's 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 the Company's legacy 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 was acknowledged as forgiven by Quest Diagnostics based upon milestone achievement.

The Company believed that in September 2009 when the United States Food and Drug Administration (the "FDA") cleared its 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 disputed whether this milestone had been achieved.

The dispute regarding the balance of the loan was resolved on March 11 , 2015 for a payment to Quest Diagnostics totaling $1,069,000 .

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 stated that if a party failed to cure material defaults within 90 days of the date of the notice of default, the other party had the right to terminate the Strategic Alliance Agreement. Quest Diagnostics disputed the effectiveness of the Company's 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 could 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. As a result of ongoing negotiations, on March 11, 2015, we reached a settlement agreement with Quest Diagnostics that terminated all disputes related to our prior strategic alliance and loan agreements. We also entered into a new commercial agreement with Quest Diagnostics . Pursuant to this agreement, Vermillion's wholly-owned subsidiary, ASPiRA LABS, will begin to offer OVA1 testing to Quest Diagnostics customers. We expect Quest Diagnostics to transfer all OVA1 U.S. testing services to ASPiRA LABS, starting with 39 states this year, while continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing for a period of two years from the date of the agreement. Pursuant to the agreement , Quest Diagnostics will also continue to offer OVA1 services through its own labs in the remaining 11 states, until ASPiRA LABS has obtained the state approvals required to provide those services. Quest will receive a fee for collection and logistic support services it provides. Per the terms of the agreement, we will not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers .

Accounts receivable from Quest Diagnostics totaled $167,000 and $373,000 at December 31, 2014 and 2013, respectively.

Note 4: Property and Equipment

T he components of property and equipment as of December 31, 201 4 and 201 3 were as follo ws **:**

	December 31,	
(in thousands)	**2014**	**2013**
Machinery and equipment	$ 563	$ 501
Demonstration equipment	38	33
Computer equipment and software	291	116
Furniture and fixtures	68	75
Gross property and equipment	960	725
Accumulated depreciation and amortization	(452)	(334)
Property and equipment, net	$ 508	$ 391

Depreciation expense for property and equipment was $ 141 ,000 and $ 72 ,000 for the years ended December 31, 201 4 and 201 3 , respectively.

NOTE 5 : Accrued Liabilities

The components of accrued liabilities as of December 31, 201 4 and 20 1 3 were as follows:

	December 31,	
(in thousands)	**2014**	**2013**
Payroll and benefits related expenses	$ 905	$ 548
Collaboration and research agreements expenses	338	187
Professional services	598	262

Tax-related liabilities	23	42
Other accrued liabilities	337	244
Total accrued liabilities	$ 2,201	$ 1,283

NOTE 6: Commitments and Contingencies

Operating Leases

The Company lease s facilities to support its business of discovering, developing and commercializing diagnostic tests in the fields of gynecologic disease . Vermillion leases its principal facility and CLIA laboratory located near Austin, Texas. The leases include an annual base rent of $130,000 and annual estimated common area charges, taxes and insurance of $62,000 and expire at various times prior to May 31, 201 6 .

Rental expense under operating leases for the years ended December 31, 201 4 and 201 3 totaled $ 130, 000 and $96,000 , respectively.

Noncancelable Collaboration Obligations and Other Commitments

Vermillion ha s 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 diseas e through March 2016. At December 31, 2014, Vermillion was obligated to pay JHU $625,000 in collaboration support through the expiration of the agreement in March 2016. Collaboration expenses under the JHU collaboration were $1,323,000 and $658,000 for the years ended December 31, 201 4 and 201 3 , 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 .

Contingent Liabilities

F rom time to time, the Company is involved in legal proceedings and regulatory proceedings arising from operations. The Company establish es reserves for specific liabilities in connection with legal actions that management deem s 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

2014 Private Placement Sale

On December 23, 2014, the Company completed a private placement pursuant to which certain investors purchased 6,944,445 shares of Vermillion common stock at a price of $1.44 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 $10,521,000 (net proceeds of approximately $10,281,000 after deducting offering expenses). The warrants are exercisable, beginning on June 23, 2015, for 4,166,659 shares of Vermillion common stock at $2.00 per share and expire on December 23, 2017.

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 $2,970,000 and for the common stock is $7,311,000 .

Other 2014 Equity Offerings

In October 2014, the Company established an at-the-market offering program, pursuant to which it may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $15.0 million. The Company is obligated to pay a commission of up to 3.0% of the gross proceeds from the sale of shares of Vermillion common stock in the offering. The Company is not obligated to sell any shares of Vermillion common stock in the offering. During the year ended December 31, 2014, approximately 48,473 shares of the Vermillion common stock were sold under the program for aggregate proceeds of $75,000 (no net proceeds after deducting offering costs). The Company suspended the program on December 24, 2014.

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 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 2013 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 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, 2014 and 2013 were as follows:

Issuance Date	Expiration Date	Exercise Price per Share	Number of Shares Outstanding under Warrant December 31, 2014	December 31, 2013
May 1, 2012	April 30, 2014	$ 3.18	-	21,000
November 1, 2012	October 31, 2014	$ 1.93	-	21,000
May 1, 2013	April 30, 2015	$ 1.88	21,000	21,000
May 13, 2013	May 13, 2016	$ 1.46	413,359	413,359
November 1, 2013	October 31, 2015	$ 3.89	21,000	21,000
May 1, 2014	April 30, 2016	$ 4.70	7,000	-
December 23, 2014	December 23, 2017	$ 2.00	4,166,659	-
			4,629,018	497,359

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, 201 4 and 201 3 was as fol lows :

(In thousands, except per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
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)
Year ended December 31, 2014:			
Net loss - basic	$ (19,209)	36,082,414	$ (0.53)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards	-	-	
Net loss - diluted	$ (19,209)	36,082,414	$ (0.53)

Due to net losses for the years ended December 31, 201 4 and 201 3 , diluted loss per share is calculated using the weighted average number of common shares outstanding and excludes the effects of potential shares of common stock 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, 201 4 and 201 3 were as follows:

	Year Ended December 31, 2014	2013
Stock options	1,711,046	1,447,968
Stock warrants	4,629,018	497,359
Restricted stock units	-	1,667
Potential common shares	6,340,064	1,946,994

NOTE 9: Employee Benefit Plans

2000 Stock Plan

Under the Amended and Restated 2000 Stock Plan (the "2000 Plan"), options could 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 15,000 and 125,000 shares of common stock were exercised during the years ended December 31, 2014 and 2013, respectively. As of December 31, 2013, options to purchase 57,900 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

Under the 2010 Plan, employees, directors and consultants of the Company are eligible to receive awards. The 2010 Plan is administered by the Compensation Committee of the Vermillion Board of Directors. 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 originally provided for issuance of up to 1,322,983 shares of Vermillion common stock , 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 163,490 and 246,348 shares of common stock were exercised during the year ended December 31, 2014 and 2013, respectively.

During the year ended December 31, 2014, the Company issued to the Vermillion Board of Directors 103,500 shares of restricted stock from the 2010 Plan having a fair value of $320,000 as payment for services rendered in 2014. During the year ended December 31, 2013, the Company issued to the Vermillion Board of Directors 160,938 shares of restricted stock from the 2010 Plan having a fair value of $334,000 as payment for services rendered in 2013.

The activity related to shares available for grant under the 2000 Plan and the 2010 Plan for the years ended December 31, 2014 and 2013 was as follows:

	2000 Stock Plan	2010 Stock Option Plan	Total
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
Options canceled	124,397	945,826	1,070,223
Reduction in shares reserved	(124,397)	-	(124,397)
Options granted	-	(1,512,000)	(1,512,000)
Restricted stock units granted	-	(128,500)	(128,500)
Restricted stock units canceled	-	11,667	11,667
Shares available at December 31, 2014	-	737,434	737,434

The stock option activity under the 2000 Plan and 2010 Plan for the years ended December 31, 2014 and 2013 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
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
Granted	1,512,000	2.58		
Exercised	(178,699)	1.34		
Canceled	(1,070,223)	3.77		
Options outstanding at December 31, 2014	1,711,046	$ 2.62	$ 178	7.82
Shares exercisable:				
December 31, 2014	729,094	$ 2.95	$ 72	5.78
Shares expected to vest:				
December 31, 2014	805,201	$ 2.38	$ 106	9.34

The range of exercise prices for options outstanding and exercisable at December 31, 2014 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	- $ 1.30		42,500	$ 1.30	9.95	-	$ -
1.31	- 2.12		713,083	1.80	6.77	413,025	1.84
2.13	- 3.09		724,874	2.70	8.83	203,923	2.95
3.10	- 9.92		208,003	3.50	8.16	89,560	3.66
9.93	- 28.65		22,586	20.28	1.43	22,586	20.28
$ 0.01	- $ 28.65		1,711,046	$ 2.62	7.82	729,094	$ 2.95

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2014	$ 55	$ 655
Year ended December 31, 2013	$ 291	$ 550

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, 2014 and 2013 were as follows:

	Year Ended December 31,	
	2014	2013
Dividend yield	- %	- %
Volatility	80 %	79 %
Risk-free interest rate	1.92 %	1.91 %
Expected lives (years)	6.0	6.0
Weighted average fair value	$ 1.78	$ 1.50

The allocation of stock-based compensation expense by functional area for the years ended December 31, 2014 and 2013 was as follows:

(in thousands)	Year Ended December 31, 2014	2013
Research and development	$ 136	$ 74
Sales and marketing	259	163
General and administrative	742	602
Total	$ 1,137	$ 839

As of December 31, 201 4 , total unrecognized compensation cost related to nonvested stock option awards was approximately $1,371,000 and the related weighted average period over which it is expected to be recognized was 3.03 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, 2014 and 2013 , the Company did not contribute to the 401(k) Plan.

NOTE 10: Income Taxes

F or the years ended December 31, 2014 and 2013 the entire net loss was generated from domestic operations.

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 the Company's operating losses. Accordingly, the Company has provided a full valuation allowance against the net deferred tax assets at December 31, 2014 and 2013. There was no income tax expense or benefit for the years ended December 31, 2014 or 2013.

The components of deferred tax assets (liabilities) at December 31, 2014 and 2013 were as follows:

(in thousands)	Year Ended December 31, 2014	2013
Deferred tax assets:		
Depreciation and amortization	$ 7,805	$ 8,698
Other	1,358	1,651
Net operating losses	58,276	54,005
Total deferred tax assets	67,439	64,354
Valuation allowance	(67,431)	(64,346)
Net deferred tax assets	$ 8	$ 8
Deferred tax liabilities:		
Other	$ (8)	$ (8)
Total deferred tax liabilities	$ (8)	$ (8)
Net deferred tax asset (liability)	$ -	$ -

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2014 and 2013 was as follows:

	Year Ended December 31, 2014	2013
Tax at federal statutory rate	34 %	34 %
State tax, net of federal benefit	1	2
Valuation allowance	(16)	(39)

Change in warrant valuation	-	-
Net operating loss and credit reduction due to section 382 limitations	-	-
Permanent items	(3)	(1)
Other	(16)	4
Effective income tax rate	- %	- %

As of December 31, 201 4 , the Company had a net operating loss of approximately $165,000,000 for federal and $140,000,000 for state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2025 for federal purposes and 2016 for state purposes. In 2016, approximately $5,000,000 of the Company's state net operating loss will expire. 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.

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 valuation allowance was $70,000,000 and $64,000,000 at December 31, 2014 and 2013, respectively. The increase of $6,000,000 between 2014 and 2013 is primarily due to adjustments to the domestic deferred tax assets related net operating losses.

The Company file s income tax returns in the U.S. and in various state jurisdictions with varying statutes of limitations. The Company has n ot been audited by the Internal Revenue Service or any state income or franchise tax agency. As of December 31, 2014, the Company's f ederal returns for the years ended 2011 through the current period and most state returns for the years ended 2010 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 2011 and 2010, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2013 reflect research and development carryforwards of $5,040,000 and $5,024,000 , respectively. The Company has recognized additional deferred tax assets for federal and California research and development credits of $148,000 and $111,000 for the year ended December 31, 2014, respectively. As of December 31, 2014, the Company's gross unrecognized tax benefits are approximately $10,322,000 which are attributable to research and development credits. A reconciliation of the change in the Company's unrecognized tax benefits is as follows:

(in thousands)	Federal Tax	State Tax	Total
Balance at December 31, 2012	$ 5,655	$ 5,242	$ 10,897
Increase in tax position during 2012	72	54	126
Decrease due to expirations	(687)	(272)	(959)
Balance at December 31, 2013	$ 5,040	$ 5,024	$ 10,064
Increase in tax position during 2014	148	111	259
Decrease due to expirations	-	-	-
Balance at December 31, 2014	$ 5,188	$ 5,135	$ 10,323

The increase for the year ended December 31, 2014 relates to a tax position taken during the current year. The increase for the year ended December 31, 2013 is related to tax positions taken during 2013 and prior years. If the unrecognized income tax benefit is recognized, all of it would impact the effective tax rate in the period in which each of the benefits is recognized.

The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. The Company recognizes interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations. The Company has not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2014 and 2013. Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

NOTE 11: Other Related Party Transactions

On October 23, 2014, the Company appointed Valerie Palmieri as Chief Operating Officer ("COO"). Vermillion was party to a consulting agreement with a company owned by the COO to provide laboratory operations and commercialization consulting services to Vermillion. The Company made payments of $340,000 for services provided pursuant to the consulting agreement through September 30, 2014. The consulting agreement was terminated as of October 23, 2014 . In connection with the work performed under the consulting agreement, the Company granted Ms. Palmieri 15,000 shares of restricted stock under the 2010 Plan having a fair value of approximately $31,000 for achievement of certain milestones. Ms. Palmieri was named President and Chief Executive Officer effective January 1, 2015.

On October 10, 2014 , the Company entered into a consulting agreement with David Schreiber, a member of Vermillion's Board of Directors. Pursuant to the terms of the consulting agreement, Mr. Schreiber provided consulting services regarding finance and corporate strategy and was paid $375 per hour. For the year ended December 31, 2014, the total amount of consulting fee expense for Mr. Schreiber was $22,375 .

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 31 , 201 5

/s/ Valerie B. Palmieri
Valerie B. Palmieri
President and Chief Executive Officer (Principal Executive Officer)

Date: March 31 , 201 5

/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.

Name	Title	Date
/s/ Valerie B. Palmieri Valerie B. Palmieri	President and Chief Executive Officer (Principal Executive Officer)	March 31 , 201 5
/s/ Eric J. Schoen Eric J. Schoen	Vice President, Finance and Chief Accounting Officer (Principal Financial Officer)	March 31 , 201 5
/s/ James T . LaFrance James T. LaFrance	Chairman of the Board of Directors	March 31 , 201 5
/s/ James S. Burns James S. Burns	Director	March 31 , 201 5
/s/ Robert S. Goggin Robert S. Goggin, III	Director	March 31 , 201 5
/s/ Veronica G. H. Jordan Veronica G. H. Jordan	Director	March 31, 2015
/s/ Peter S. Roddy Peter S. Roddy	Director	March 31 , 201 5
/s/ David Schreiber David Schreiber	Director	March 31, 2015

/s/ Carl Severinghaus Carl Severinghaus	Director	March 31 , 201 5
/s/ Eric Varma Eric Varma	Director	March 31 , 201 5

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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 Correlogic 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	
3.23.3	Certificate of Amendment of Fourth Amended Certificate of Incorporation, effective June 19, 2014	8-K	001-34810	3.23.3	August 14, 2014	
	Fifth Amended and Restated Bylaws of Vermillion, Inc., as amended effective June 19 , 2014	8-K	001-34810		August 14, 201 4	
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	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	
4.3	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	

4.4	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
4.5	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
4.6	Vermillion, Inc. Common Stock Purchase Warrant issued to Liolios Group, Inc. on November 1, 2012	S-3	333-198734	4.5	September 15, 2014
4.7	Vermillion, Inc. Common Stock Purchase Warrant issued to Liolios Group, Inc. on May 1, 2013	S-3	333-198734	4.6	September 15, 2014
4.8	Vermillion, Inc. Common Stock Purchase Warrant issued to Liolios Group, Inc. on November 1, 2013	S-3	333-198734	4.7	September 15, 2014
4.9	Vermillion, Inc. Common Stock Purchase Warrant issued to Liolios Group, Inc. on May 1, 2014	S-3	333-198734	4.8	September 15, 2014
4.10	Form of Vermillion, Inc. Common Stock Purchase Warrant, issued on May 13, 2013	S-3	333-198734	4.4	September 15, 2014
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
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	Employment Agreement between Vermillion, Inc. and Marian Sacco dated December 16, 2013#	8-K	001-34810		December 17, 2013	
10.20	Vermillion, Inc. Amended and Restated 2010 Stock Incentive Plan #	8-K	001-34810	10.1	December 17, 2013	
10.21	Employment Agreement between Eric J . Schoen and Vermillion, Inc. dated April 4, 2012 #	8-K	001-34810	10.1	April 10, 2012	
10.22	Offer letter from Vermilllion, Inc. to Donald G. Munroe dated September 20, 2011#	8-K	001-34810	10.1	September 26, 2011	
10.23	Employment Agreement between Bruce A. Huebner and Vermillion, Inc. dated November 26, 2012 #	8-K	001-34810	10.1	November 28, 2012	
10.24	Consulting Agreement between David Schreiber and Vermillion, Inc. dated October 10, 2014					√
10.25	Consulting Agreement between David Schreiber and Vermillion, Inc. dated November 5, 2014					√
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					√
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.

CONSULTING AGREEMENT

This Consulting Agreement (" Agreement ") confirms the understanding between David Schreiber (" Schreiber ") and Vermillion, Inc. pursuant to which the Company has retained Schreiber to provide consulting services of the type described below (collectively, the " Services "), on the terms and subject to the conditions set forth herein, in connection with the matters referred to herein.

1. Scope of Services and Compensation

(a) Schreiber agrees to perform for the Company, beginning immediately upon the signing of this Agreement, the Services in relation to the Company's evaluation and assessment of the feasibility of various business strategies as outlined by the Company's VP, Finance or other executive officer.

(b) Schreiber will also perform other duties from time to time as are reasonably requested by Company and agreed to by Schreiber.

(c) During the term of this Agreement, Schreiber will be paid $375-per hour for performing the Services. Travel time will not be billed for.

(d) The Company shall make payments for Services to Schreiber promptly upon presentation of a statement of services rendered. Schreiber will invoice the Company on a monthly basis.

(e) The Company shall reimburse Schreiber for his reasonable out of pocket costs, including meals, travel, lodging, parking and other expenses incurred in connection with the performance of his duties under this Agreement. Travel time is not billed for.

2. Period of Performance and Exclusivity

(a) Unless otherwise extended by the parties, this Agreement shall run for an initial period of three (3) months from the date hereof (the " Initial Term "), and shall automatically renew for additional three (3) month terms unless either party provides written notice of its intent not to renew (in each case, if any, a " Renewal Term "). The Initial Term and any Renewal Terms shall constitute the " Term ".

3. Termination .

(a) This Agreement may be terminated by either Schreiber or the Company at any time upon five (5) days prior written notice. Upon such a termination, Schreiber shall be entitled to all accrued payments and reimbursement of expenses permissible under this Agreement and due to him on the date of termination. In addition, if this Agreement is terminated by the Company before the conclusion of the Term, Schreiber shall be entitled to receive any amounts due pursuant to the minimum guaranty payment set forth in Section 1(c).

(b) The parties acknowledge that the provisions of Sections 1, 4 and other provisions, which may be reasonably interpreted to be intended to do, so shall survive the expiration or termination of this Agreement.

4. Indemnification .

The Company shall indemnify and hold harmless Schreiber from and

against any and all claims, damages, losses and judgments (including reasonable attorneys' fees and costs) arising from or related to this Agreement, except to the extent that the matter giving rise to such claim for indemnity was the result of fraud, bad faith, recklessness, willful misconduct, the commission of a felony or the gross negligence of Schreiber.

5. Contractual Relationship

In performing the services under this Agreement, Schreiber shall operate as, and have the status of, an independent contractor. Schreiber shall not have authority to enter into any contract binding the Company or create any obligations on the part of the Company except as shall be specifically authorized by the Company. The Company and Schreiber will be mutually responsible for determining methods for performing the services described in Section 1 hereof.

6. Representatives and Notices

All notices provided for herein shall be in writing, and may be served personally to the Fund representative or its assigns and/or a representative of Schreiber, at their respective places of business, or by registered mail to the address of each party, or may be transmitted by facsimile.

7. Arbitration/Jurisdiction of the Court

Any claim or controversy arising out of, or relating to, this agreement, or breach thereof, which is not settled between the signatories themselves, shall be settled by an independent arbitrator, mutually acceptable to both parties. Jurisdiction for any legal action is stipulated by the parties to lie in the State of New York.

8. Miscellaneous

This Agreement constitutes the entire agreement between the Company and Schreiber relating to the provisions of the Services on and after the date of this Agreement and may not be assigned without the prior written consent of the other party. It supersedes all prior communications, representations or agreements, whether oral or written, with respect to the subject matter hereof, and has not been induced by any representations, statements or agreements other than those expressed herein. No agreements, hereafter made between the parties shall be binding on either party unless reduced to writing and signed by an authorized officer of the party bound. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement shall be, in all respects, interpreted and construed, and the rights of the parties hereto governed, by the laws of the State of New York without regard to its conflicts of laws provisions.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto, intending to be legally bound, have caused this Consulting Agreement to be executed as of this 10th day of October, 2014.

Austin, TX 78738

By: /s/ David Schreiber

Name: David Schreiber

Date: October 10, 2014

Vermillion, Inc.

By: /s/ Eric Schoen

Name: Eric Schoen

Title: VP , Finance & CAO

CONSULTING AGREEMENT

This Consulting Agreement ("Agreement") confirms the understanding between David Schreiber ("Schreiber") and Vermillion pursuant to which the Company has retained Schreiber to provide consulting services of the type described below (collectively, the " Services "), on the terms and subject to the conditions set forth herein, in connection with the matters referred to herein.

1. Scope of Services and Compensation

(a) Schreiber agrees to perform for the Company, beginning immediately upon the signing of this Agreement, the Services in relation to the Company's evaluation and assessment of the feasibility of various business strategies as outlined by the Company's CEO.

(b) Schreiber will also perform other duties from time to time as are reasonably requested by Company and agreed to by Schreiber

(c) During the term of Agreement, Schreiber will be paid $375-per hour performing the Services. Notwithstanding the preceding sentence, Schreiber will be paid a minimum of $37,5 00 for the three-month period from the date hereof (which represents compensation for 100 hours of Services.) Travel time will not be billed for.

(d) The Company shall make payments for Services to Schreiber promptly upon presentation of a statement of services rendered. Schreiber will invoice the Company on a monthly basis.

(e) The Company shall reimburse Schreiber for his reasonable out of pocket costs, including meals, travel, lodging, parking and other expenses incurred connection with the performance of his duties under this Agreement. Travel time will not be billed for.

2. Period of Performance and Exclusivity

(a) Unless otherwise extended by the parties, the Agreement shall run for an initial period of three (3) months from the date hereof (the " Initial Term "), and shall automatically renew for additional three (3) month terms unless either party provides written notice of its intent not to renew (in each case, if any, a " Renewal Term "). The Initial Term and any Renewal Terms shall constitute the " Term ".

(b) During the term of this Agreement, Schreiber shall not perform Services related to the Company's business for any person during the term of this Agreement other than the Company, or an affiliate of the Company, without the Company's prior written consent.

3. Termination

(a) The Agreement may be terminated by either Schreiber or the Company at any time upon five (5) days prior written notice. Upon such a termination, Schreiber shall be entitled to all accrued payments and reimbursement of expenses permissible under this Agreement and due to him on the date of termination. In Addition, if this Agreement is terminated by the

Company before the conclusion of the Term, Schreiber shall be entitled to receive any amounts due pursuant to the minimum guaranty payment set forth in Section 1(c).

(b) The parties acknowledge that the provisions of Sections 1, 4 and other provisions, which may be reasonably interpreted to be intended to do, so shall survive the expiration or termination of this Agreement.

4. Indemnification

(a) The Company shall indemnify and hold harmless Schreiber from and against any and all claims, damages, losses and judgements (including reasonable attorneys' fees and costs) arising from or related to this Agreement, except to the extent that the matter giving rise to such claim for indemnity was the result of fraud, bad faith, recklessness, willful misconduct, the commission of a felony or the gross negligence of Schreiber.

5. Contractual Relationship

In performing the services under this Agreement, Schreiber shall operate as, and have the status of, an independent contractor. Schreiber shall not have authority to enter into any contract binding the Company or create any obligations on the part o f the Company except as shall be specifically authorized by the Company. The Company and Schreiber will be mutually responsible for determining methods for performing the Services described in Section 1 hereof.

6. Representatives and Notices

All notices provided for herein shall be in writing, and may be served personally to the Fund representative or its assigns and/or a representative of Schreiber, at their respective places of business, or by registered mail to the address of each party, or may be transmitted by facsimile.

7. Arbitration/Jurisdiction of the Court

Any claim or controversy arising out of, or relating to, this Agreement, or breach thereof, which is not settled between the signatories themselves, shall be settled by an independent arbitrator, mutually acceptable to both parties. Jurisdiction for any legal action is stipulated by the parties to lie in the State of New York.

8. Miscellaneous

This Agreement constitutes the entire agreement between the Company and Schreiber relating to the provisions of the Services on and after the date of this Agreement and may not be assigned without the prior written consent of the other party. It supersedes all prior communications, representations or agreements, whether oral or written, with respect to the subject matter hereof, and has not been induced by any representations, statements or agreements other than those expressed here. No agreements, hereafter made between the parties shall be binding on either party unless reduced to writing and signed by an authorized officer of the party bound. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement shall be, in all respects, interpreted and construed, and the rights of the parties hereto governed, by the laws of the State of New York without regard to its conflicts of laws provisions.

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, the parties hereto, intending to be legally bound, have caused this Consulting Agreement to be executed as of this 5th day of November, 2014.

Austin, TX 78738

By: /s/ David Schreiber

Name: David Schreiber

Date: November 5, 2014

Vermillion, Inc.

By: /s/ James LaFrance

Name:

Title: CEO

Exhibit 21.0

Vermillion, Inc. Subsidiaries

December 31, 2014

SPiRA L

Subsidiary	State/Country of Incorporation/Formation
IllumeSys Pacific, Inc.	California
Ciphergen Technologies, Inc.	California
ASPiRA Labs, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Vermillion, Inc.
Austin, Texas

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-189929 and 333-198734) and Form S-8 (Nos. 333-167204 and 333-193312) of Vermillion, Inc. of our report dated March 31, 2015, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP
Austin, Texas

March 31, 2015

Exhibit 31.1

CERTIFICATION

I, Valerie B. Palmieri, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2014 of Vermillion, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disc losure controls and procedures (as defined in Exchange Ac t Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Ac t Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31 , 2015

/s/ Valerie B. Palmieri

Valerie B. Palmieri

President and Chief Executive Officer

(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Eric J. Schoen, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2014 of Vermillion, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disc losure controls and procedures (as defined in Exchange Ac t Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Ac t Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

X

Date: March 31, 2015

/s/ Eric J. Schoen

Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)

Exhibit 32.0

Certifica tion

Pursuant to 18 U.S.C. Section 1350,

as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

with Respect to the Annual Report on Form 10-K

for the Year Ended December 31, 2014

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, Chapter 63 of Title 18, United States Code), each of the undersigned officers of Vermillion, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

1. The Company's annual report on Form 10-K for the year ended December 31, 2014, (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and
2. The i nformation contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Bruce A.
Huebner

Date: March 31, 2015

/s/ Valerie B.
Palmieri

Valerie B. Palmieri

President and Chief Executive Officer

(Principal Executive Officer)

Date: March 31, 2015

/s/ Eric J.
Schoen

Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed as part of the Form 10-K or as a separate disclosure document of the Company or the certifying officers.