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, 2016.

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

Commission file number: 001-34810

Vermillion, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0595156**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

12117 Bee Caves Road, Building Three, Suite 100

Austin, Texas	**78738**
(Address of Principal Executive Offices)	(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 exchange 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 was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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 (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer ☐	Accelerated filer ☐
Non - accelerated filer ☐	Smaller reporting company ☒

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

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

The aggregate market value of voting common stock held by non-affiliates of the registrant is $31,814,733

and is based upon the last sales price as quoted on The NASDAQ Capital Market as of June 30, 2016.

As of March 24, 2017, the registrant had 56,089,245 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information from the registrant's definitive Proxy Statement for its Annual Meeting of Stockholders, scheduled to be held on June 21, 2017, 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, 2016.

VERMILLION, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2016

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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, cost of revenue, operating expenses, cash flow, results of operations and financial condition;
- our plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders;
- our planned business strategy and the anticipated timing of the implementation thereof;
- plans with respect to our market expansion and growth, including plans to market Overa outside the United States;
- plans to develop new algorithms and molecular diagnostic tests;
- plans to establish our own payer coverage for OVA1 and Overa;
- 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;
- plans to leverage infrastructure and enhance our pipeline of future technologies by fostering relationships with in vitro diagnostic (“IVD”) companies;
- plans with respect to ASPiRA IVD, Inc. (“ASPiRA IVD”);
- expected service revenue growth based on ASPiRA IVD;
- expected license revenue in future periods;
- our planned focus on the execution of five core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to address unmet medical needs for women faced with gynecologic disease and other conditions and the continued development of our business;
- anticipated efficacy of our products, product development activities and product innovations;
- expected competition in the markets in which we compete;
- plans with respect to ASPiRA LABS, Inc. (“ASPiRA LABS”);
- expectations regarding future services provided by Quest Diagnostics Incorporated (“Quest Diagnostics”);
- plans to expand our ovarian cancer franchise beyond OVA1, including with respect to Overa and OvaX;
- plans regarding the commercialization of Overa;
- plans to develop and perform laboratory development tests (“LDTs”);
- plans with respect to the Company’s pelvic mass registry, including anticipated sources of funding;
- anticipated effects on reimbursement for OVA1 from changes to Novitas Solutions’ administrative requirements;
- expectations regarding the Company’s approach of monitoring and combining multiple protein biomarkers to create diagnostic tests to aid physicians considering treatment options for patients with complex diseases, and the Company’s future development of new IVDMIA (also known as In Vitro Diagnostic Multivariate Index Assays);
- expectations regarding existing and future collaborations and partnerships;
- plans regarding future publications;

- our continued ability to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests outside the United States;
- our ability to obtain and maintain the regulatory approvals required to market Overa in other countries;
- our continued ability to expand and protect our intellectual property portfolio;
- anticipated liquidity and capital requirements;
- anticipated future losses and our ability to continue as a going concern;
- expectations regarding the second disbursement from our financing arrangement with the State of Connecticut Department of Economic and Community Development ("DECD");
- expected expenditures, including the expected decrease in expenses related to research and development in 2017;
- our ability to use our net operating loss carryforwards;
- expected market adoption of our diagnostic tests, including OVA1 and Overa;
- expectations regarding our position in the gynecologic health markets to enable us to launch new products developed, licensed, co-marketed or acquired by various routes;
- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations; 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.

Forward-looking 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 or Overa sales; our ability to market our test through sales channels other than Quest Diagnostics, including ASPiRA LABS; failures by third-party payers to reimburse OVA1 or Overa 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 Overa both within and outside the United States; in the event that we succeed in commercializing Overa 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 Food and Drug Administration ("FDA") requirements for production, marketing and post-market monitoring of our products; additional costs that may be required to make further improvements to our manufacturing operations; 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 its operating costs; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; and our ability to comply with FDA regulations that relate to our products and to obtain any FDA clearance or approval required to develop and perform LDTs.

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 both benign and malignant gynecologic disease, with our primary focus being diseases of the female pelvic cavity.

We have expanded our corporate strategy with the goal of transforming the Company 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 is being deployed in three phases. The three phases are a rebuild phase, which was completed in the third quarter of 2015, a transformation phase, which is ongoing, and a market expansion and growth phase, which we expect to begin in 2017.

During the first phase, we expanded our leadership team by hiring several new senior leaders including 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 completed the process of obtaining licensure of ASPiRA LABS in all of the states that require licenses, are in the process of

establishing our own payer coverage for OVA1, Multivariate Index Assay (MIA), and launched a second-generation OVA1 test, trademarked Overa, Multivariate Index Assay, 2nd Generation (MIA2G), on a targeted basis. In the third phase, we plan to fully commercialize Overa by utilizing the full national licensure of ASPiRA LABS, select laboratories for distribution, managed care coverage in select markets, our sales force and existing customer base. Unlike OVA1, Overa uses a global testing platform, which will allow Overa to be deployed internationally. We initiated the targeted launch of Overa in October 2016 with two key accounts converting from OVA1 to Overa. In October 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union. We also plan to develop an LDT product series, which we refer to internally as OvaX. We anticipate that OvaX will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value.

In February 2016, we adopted a plan to streamline our organization. We restructured headcount and other expenses targeting an approximately 20% reduction in operating expenses in 2016, as compared to operating expenses in 2015.

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 biomarkers, other modalities 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 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.

Business: Our initial product, OVA1, is a blood test designed to, in addition to a physician's clinical assessment of a woman with a pelvic mass, identify women who are at high risk of having a malignant ovarian tumor prior to planned surgery. The FDA cleared OVA1 in September 2009, and we commercially launched OVA1 in March 2010. We have launched on a targeted basis a second-generation biomarker panel known as Overa, which is intended to maintain our product's high sensitivity while improving specificity. We received FDA clearance for Overa on March 18, 2016. Overa uses the Roche cobas 6000 platform.

In June 2014, Vermillion launched ASPiRA LABS, a Clinical Laboratory Improvement Amendments of 1988 ("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 and disease. ASPiRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based diagnostic algorithm to aid in clinical decision making and advance personalized treatment plans. The lab currently processes our OVA1 and Overa tests, and we plan to expand the testing to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPiRA LABS. ASPiRA LABS holds a CLIA Certificate of Registration and a state laboratory license in California, Florida, Maryland, New York, Pennsylvania and Rhode Island. This allows the lab to process OVA1 on a national basis. The Centers for Medicare and Medicaid Services ("CMS") issued a provider number to ASPiRA LABS in March 2015.

In 2016, we created a new service within the ASPiRA channel strategy, "an ASPiRA IVD Services Program". In April 2016, we formed ASPiRA IVD to offer IVD trial services to third-party customers. ASPiRA IVD is a specialized laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. ASPiRA IVD was built around a core of laboratory expertise and an FDA-compliant quality system, and strives to deliver accurate and reliable results to its third-party customers suitable for FDA submission. ASPiRA IVD received a CLIA laboratory license in June 2016 and commenced operations in the second quarter of 2016.

In the ASPiRA IVD program, we plan to leverage our existing infrastructure and enhance our pipeline of future technologies by fostering relationships with IVD companies that are developing new diagnostics including companion diagnostics platforms. We believe this plan will allow us to continue to be innovative in evaluating potential diagnostics. Our goal with the addition of this line of business is to invest in our short-term and long-term enterprise value while leveraging specimen bank, database, FDA experience, laboratory informatics and operating efficiency.

Strategy: We are focused on the execution of five core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to build long-term value for our investors:

- Maximizing the existing OVA1 opportunity in the United States by taking the lead in payer coverage and commercialization of OVA1. This strategy included the launch of a CLIA certified clinical laboratory, ASPiRA LABS, in June 2014;

- Improving OVA1 specificity and expanding the distribution platform by launching Overa, a next generation biomarker panel, on a targeted basis while building the clinical utility and health economics foundation of both OVA1 and Overa,

which we believe may allow for better domestic market penetration and international expansion (FDA clearance for Overa was received on March 18, 2016);

- Leveraging our existing database and specimen bank while building the largest specimen and data repository of gynecologic pelvic mass patients worldwide;

- Expanding our product offerings to additional pelvic disease conditions such as endometriosis and polycystic ovarian syndrome ("PCOS") 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; and

- Expanding our customer offerings with the launch of our ASPiRA IVD laboratory services.

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.

Our Product

OVA1 addresses a clear clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary 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 May 2015, we announced that the Company was approved for a product development grant from the Cancer Prevention and Research Institute of Texas ("CPRIT") for $7,500,000, to help fund the Company's new multi-site pelvic mass registry of patients undergoing evaluation, diagnosis, treatment and follow up for pelvic masses that may lead to gynecological malignancy. Receipt of the grant award was subject to execution of a grant contract with CPRIT. However, the Company and CPRIT were unable to reach mutually agreeable terms on the grant contract and terminated negotiations on August 8, 2016. The Company now intends to fund its pelvic mass registry by utilizing its own resources and pursuing partnerships with third parties.

In May 2016, we entered into our first international distribution agreement for Overa. Pursuant to this agreement, Bio-Medical Science Co., Ltd. has the right to market and distribute Overa on an exclusive basis in South Korea. Subsequently, we executed exclusive international distribution agreements for Overa with Pro-Genetics LTD in Israel and MacroHealth, Inc. in the Philippines. The MacroHealth agreement is our first decentralized international agreement with Overa specimen testing to be performed in the Philippines.

In October 2016, we launched our pelvic mass specimen and data repository and began the collection of patient consents under Institutional Review Board ("IRB") for collection and cataloguing of serum samples for future research purposes.

In November 2016, The American College of Obstetricians and Gynecologists ("ACOG") issued Practice Bulletin Number 174 which included OVA1 as a "Multivariate Index Assay". This bulletin outlines ACOG's "new" clinical management guidelines for adnexal mass management.

These new clinical management guidelines replace the July 2007 version, Practice Bulletin Number 83. Practice Bulletins summarize current information on techniques and clinical management issues for the practice of obstetrics and gynecology. Practice Bulletins are evidence-based documents, and recommendations are based on the evidence. This is also the only clinical management tool used for adnexal masses. Guidelines do not exist for adnexal masses, only Practice Bulletins. Guidelines do exist, however, for ovarian cancer management.

The Practice Bulletin recommends that obstetricians and gynecologists evaluating women with adnexal masses who do not meet Level A criteria of a low risk transvaginal ultrasound should proceed with Level B clinical guidelines. Level B guidelines state

that the physician may use risk assessment tools such as existing CA125 technology or OVA1 as listed in the bulletin. Based on this, OVA1 has now achieved parity with CA125 as a Level B recommendation for the management of adnexal masses, but OVA1 is the only recommended Level B tool *that has FDA clearance for use* assessing ovarian cancer risk in women of all stages, ages, and cancer types..

In December 2016, we received an FDA Clarification Letter regarding OVA1 and Overa. This letter was in reference to the September 7, 2016 FDA Safety Communication advising women and their physicians against the use of ovarian cancer screening tests for asymptomatic women.

In order to avoid any confusion, as well as to document the FDA position on OVA1 and Overa, Jeffrey Shuren, M.D, J.D, Director for the Center for Devices and Radiological Health at the FDA, sent a letter to Vermillion, dated December 21, 2016. In the letter, Dr. Shuren stated: "We agree that this safety communication does not apply to Vermillion's FDA-cleared tests, OVA1 (MIA) and Overa (MIA2G), which are not screening tests for ovarian cancer."

"FDA cleared OVA1 (MIA) and Overa (MIA2G) as aids to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The intended uses of the two assays are the same—to help physicians more reliably identify which patients would benefit from consultation with or referral to a gynecologic oncologist. OVA1 (MIA) and Overa (MIA2G) are indicated for women who present with an adnexal mass."

In March 2015, we entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Vermillion's wholly-owned subsidiary, ASPiRA LABS, as of August 10, 2015. Pursuant to this agreement, as amended as of March 11, 2017, Quest Diagnostics is continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing through at least March 11, 2018 in exchange for a market value fee. Per the terms of the new commercial 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 reflecting the diverse nature of the clinical centers at which ovarian adnexal masses are evaluated.[1] The results of the clinical trial demonstrated that in a clinical cohort of 516 patients, OVA1, in conjunction with clinical evaluation, was able to identify 95.7% (154/161) of the malignant ovarian tumors overall, and to rule out malignancy with a negative predictive value ("NPV") of 94.6% (123/130). At the 2010 International Gynecologic Cancer Society Meeting, data was presented demonstrating the high sensitivity of OVA1 for epithelial ovarian cancers; OVA1 detected 95 out of 96 epithelial ovarian cancer cases for a sensitivity of 99.0%, including 40/41 stage I and stage II epithelial ovarian cancers. These findings resulted in an overall sensitivity of 97.6% for early stage epithelial ovarian cancers, as compared to 65.9% for the previous single-marker CA125 test using the ACOG cutoffs. The improvement in sensitivity was even greater among premenopausal women; for OVA1, sensitivity for early stage epithelial ovarian cancer in premenopausal women was 92.9% compared to CA125 with a 35.7% sensitivity. Overall, OVA1 detected 76% of malignancies missed by the CA125 assay, including all advanced stage malignancies. OVA1 is not indicated for use as a screening or stand-alone diagnostic assay. The study results were published in *Obstetrics and Gynecology* in 2011.

In February 2013, results from a second pivotal clinical study of OVA1, called the "OVA500 study" led by Dr. Robert E. Bristow, Director of Gynecologic Oncology Services at University of California Irvine Healthcare, were published in *Gynecologic Oncology*. The study evaluated OVA1 diagnostic performance in a population of 494 evaluable patients who underwent surgery for an ovarian adnexal mass by a non-gynecologic oncologist. Like the earlier OVA1 validation study, this was a prospective, multi-center study of consecutively enrolled, eligible subjects coordinated through 27 sites across the 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 a gynecologic oncologist, and for which the mass was determined to be benign or malignant following enrollment in the study.

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

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

An important additional finding related to medical necessity was the detection of early stage malignancies, since stage I cancers are 90-95% curable if appropriately operated and treated. Of the 92 malignancies in OVA500, 35 were early stage and 28 were stage I; 38.0% and 30.4% of all malignancies, respectively. OVA1 standalone sensitivity in stratifying patients as high-risk was 91.4% (32/35) for all early stage and 89.3% (25/28) for stage I malignancies, respectively. Comparatively, CA 125-II sensitivity was 65.7% (23/35) for all early stage and 64.3% (18/28) for stage I malignancies, respectively. 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.

In May 2013, the SGO issued a position statement on OVA1. This second SGO statement on OVA1 since its FDA clearance in 2009 represented 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 OVA1.

In June 2013, a study was published in *Gynecologic Oncology* analyzing the medical records of 13,321 women with epithelial ovarian cancer, the most common type of ovarian cancer, diagnosed from 1999 to 2006 in California. [3] Led by Dr. Robert Bristow, this study demonstrated that only 37% of these patients received treatment that adhered to care guidelines established by the National Comprehensive Cancer Network (“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 were featured on the front page of the New York Times under the headline, "Widespread Flaws Found in Ovarian Cancer Treatment." According to Dr. Bristow, principal investigator of the study, “If we could just make sure that women get to the people who are trained to take care of them, the impact would be much greater than that of any new chemotherapy drug or biological agent.” (NY Times, March 11, 2013, Denise Grady).

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

In 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 clinical tools and that when the OVA1 score is further stratified by imaging risk and menopausal status, there is a better understanding of the clinical risk of ovarian malignancy."

In May 2014, we announced a Vermillion-funded study with Moffitt Cancer Center in Tampa, Florida. 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.

One of these studies appeared as a poster presentation at the Annual Meeting of SGO (the Society for Gynecologic Oncology) in March 2016. The poster, titled “Inbound referral patterns for ovarian cancer patients at a NCCN institution”, evaluated the highly varying paths experienced by 345 women, which led to eventual diagnosis and referral to Moffitt. Evidence of delays, surgery by non-specialists, and significant impact on survival was found among these patients, supporting Vermillion’s contention that better pre-surgical referral is relevant to high-volume cancer care, not just under-served market segments.

In December 2015, results from a cost-effectiveness analysis study were published in the peer reviewed journal, *Current Medical Research & Opinion*. The study was co-authored by Dr. Robert E. Bristow and Dr. Gareth K. Forde, clinicians at the University of California at Irvine, and Dr. John Hornberger, a leading health economist at Stanford University School of Medicine. The 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", compared the cost-effectiveness of triaging ovarian masses using OVA1 versus two important clinical benchmarks: the CA-125 biomarker and the modified ACOG (American College of Obstetricians and Gynecologists) guideline for ovarian cancer risk assessment ("mod-ACOG").

Study endpoints included treatment costs, quality-adjusted life-years ("QALYs") and incremental cost-effectiveness ratio ("ICER"). The health economic model utilized OVA1 performance data from the OVA500 prospective trial, published survival, cost and QALY parameters, and a best-practice patient management decision tree. Several important health economic and quality outcome conclusions were reported in the 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.

In April 2015, we initiated a strategic collaboration with Kaiser Permanente's Southern California Permanente Medical Group ("SCPMG"). Vermillion has continued this strategic collaboration in order to enhance the diagnosis and treatment of ovarian cancer. The ultimate goal of this collaboration is to create a "best practice" for identification and "first time right" treatment of patients with ovarian cancer. Once data collection from the first phase of this relationship focused on retrospective benchmarking of ovarian cancer care within the SCPMG system is complete, we expect findings to be submitted for publication. Future phases, which may depend on phase one findings, may assess the potential value of OVA1 or Overa to better inform ovarian cancer referral and patient management within an integrated care setting. Vermillion's goal is to optimize the on-label testing protocol to SCPMG's practice requirements and quality metrics, thereby obtaining evidence for broader application.

In July 2016, the study on the clinical validation of Overa (MIA2G in peer review literature) was published in the American Journal of Obstetrics & Gynecology[6]. The data show significant improvement in Overa specificity compared to OVA1, while maintaining strong sensitivity (92% for OVA1 in a 2013 study). We received FDA clearance for Overa on March 18, 2016 and launched Overa on a targeted basis in October 2016.

Highlights of the publication are as follows:

Validation Study† (N=493)	OVA1	Overa (MIA2G)	Variance	% Variance
Sensitivity	n.s. (not significantly different)			
Specificity	53.6%	69.1%	+15.5%*	+28.9%
Positive predictive value	31.4%	40.4%	+9.0%*	+28.7%
Negative predictive value	n.s. (not significantly different)			
Overall clinical accuracy†	**60.9%**	**73.2%**	**+12.3%**	**+20.2%**

†Risk stratification performance, for analytical purposes only; OVA1/Overa are not standalone diagnostic tests
*Statistically significant difference ($p<0.001$); n.s. Difference not statistically significant ($p\geq0.05$)

On April 20, 2016, we announced the publication of the first clinical utility data demonstrating that identification of high-risk patients using OVA1 prior to surgery resulted in referral of nearly all patients who had primary ovarian malignancies to gynecologic oncologists. The study, entitled "The clinical utility of an elevated-risk multivariate index assay score in ovarian cancer patients," was published in the June 2016 issue of the peer-reviewed journal, *Current Medical Research & Opinion*.

On March 29, 2017, we announced the acceptance for publication of the original research titled, "Evaluation of a Validated Biomarker Test in Combination With a Symptom Index ("SI") to Predict Ovarian Malignancy. In a 2016 study performed with 218 patients who presented with pelvic masses, the combination of SI and OVA1 showed a sensitivity to detect primary ovarian malignancy of 100%, detecting both early and late stage cancers better than either SI or OVA1 alone. Additionally, the negative predictive value of SI and OVA1 combined was also 100%, indicating that all women that tested negative for both tests were certain not to have a primary ovarian malignancy.

The study surveyed physicians who frequently used OVA1, and identified 122 patients who underwent surgery for a pelvic mass after a high-risk OVA1 score was reported. Of these, 65 had a primary ovarian malignancy, while the remainder were benign or had a metastatic cancer of non-ovarian origin. Pre-surgical involvement of a gynecologic oncologist was documented, including referral, consultation or availability on stand-by; and the specialty of the surgeon who performed the adnexal surgery was also recorded. In this cohort, 80% of the patients were referred to a gynecologic oncologist, and an additional 9% had one available if needed in surgery. 94% of the initial surgeries were performed by gynecologic oncologists. Prior studies in the literature show a 33-60% referral rate in ovarian cancer patients. This is significant because the NCCN guidelines recommend that all patients with ovarian cancer undergo surgery by a gynecologic oncologist and studies have documented that treatment by a gynecologic oncologist leads to improved outcomes. The surveys also documented 48% of the primary ovarian malignancies associated with elevated risk OVA1 scores were stage I or II, supporting the clinical validation of OVA1 in detection of early stage 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"), UC Irvine and Southern California Permanente Medical Group ("SCPMG").

[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.

[6] Coleman RL, Herzog TJ, Chan DW, Munroe DG, Pappas TC, Smith A, Zhang Z, Wolf J. Validation of a second-generation multivariate index assay for malignancy risk of adnexal masses. Am J Obstet Gynecol. 2016 Jul;215(1):82.e1-82.e11

The Diagnostic Market

The economics of healthcare demand effective and efficient allocation of resources which can be accomplished through disease prevention, early detection of disease leading to early intervention, and diagnostic tools that can triage patients to more appropriate therapy and intervention. Allied Market Research, a market research and business consulting partnership, expects that IVD

market revenue will reach $74 billion by 2020. We have chosen to concentrate our business focus in the areas of oncology and women's health where we have established strong key opinion leaders, 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 and informatics 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 IVDMIA (also known as In Vitro Diagnostic Multivariate 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 considered experts 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 approximately 14,000 deaths each year in the United States. As of early 2017, The American Cancer Society ("ACS") estimated that over 22,000 new ovarian cancer cases will be diagnosed, with the majority of 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 ACS, when ovarian cancer is diagnosed at its earliest stage, the patient has a 5-year survival rate of 92%. Ovarian cancer patients have up to a 90% cure rate following surgery and/or chemotherapy if detected in stage 1. However, only 15% 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 17%.

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, we believe only about one-third of women with these types of tumors are operated on by specialists, in part because of inadequate diagnostics 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 simple ovarian cysts in women 55 years of age and older can be as high as 14%.[1] Adnexal masses are thought to be even more common in premenopausal women, but there are more non-persistent, physiologic ovarian masses in this demographic group. For instance, in the University of Kentucky ovarian cancer screening project, the rate of postmenopausal women with persistently abnormal ultrasound findings requiring surgery was 1.4%.[2] According to 2010 U.S. census data, there are 36.8 million women between the ages of 50 and 70 in the U.S., suggesting that there are more than 500,000 suspicious adnexal masses in this segment alone. Those that do require evaluation for the likelihood for malignancy could potentially benefit from the use of OVA1 or Overa.

The ACOG Ovarian Cancer Guidelines and the SGO guidelines 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 diagnostics 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.

[1] Greenlee RT, Kessel B, Williams CR, Riley TL, Ragard LR, Hartge P, Buys SS, Partridge EE, Reding DJ. Prevalence, incidence, and natural history of simple ovarian cysts among women >55 years old in a large cancer screening trial. Am J Obstet Gynecol. 2010 Apr;202(4):373.e1-9.

[2] van Nagell JR Jr, DePriest PD, Ueland FR, DeSimone CP, Cooper AL, McDonald JM, Pavlik EJ, Kryscio RJ. Ovarian cancer screening with annual transvaginal sonography: findings of 25,000 women screened. Cancer. 2007 May 1;109(9):1887-96.

Commercialization

In 2013, we offered OVA1 exclusively through Quest Diagnostics and in 2014, we offered OVA1 both through Quest Diagnostics and ASPiRA LABS. In March 2015, the Company entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Vermillion's wholly-owned subsidiary, ASPiRA LABS. Pursuant to this agreement as amended, Quest Diagnostics is continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing through at least March 11, 2018 in exchange for a market value fee. Per the terms of the commercial agreement, the Company 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 2015, our revenue was generated through Quest Diagnostics and ASPiRA LABS and, in 2016, solely through ASPiRA LABS and ASPiRA IVD. In 2017, we expect to generate revenue through ASPiRA LABS and ASPiRA IVD. Both within and outside the United States, laboratories may become customers, either directly with us or via distribution relationships established between us and authorized distributors.

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 have done 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, Inc. 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.

Our research and development expenses were $2,172,000 and $3,751,000 for the years ended December 31, 2016 and 2015, respectively. The decrease from the prior year was due primarily to completion and clearance of Overa in March 2016. In October 2016, we began the collection of patient consents under IRB for collection and cataloguing of serum samples for future research purposes at a much lower cost.

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

Addressing the Heterogeneity of Disease

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

Validation of Biomarkers Through Proper Study Design

Analysis of peer-reviewed publications reveals almost daily reports of novel biomarkers or biomarker combinations associated with specific diseases. Few of these are used clinically. As with drug discovery, preliminary research results fail to canvass sufficient variation in study populations or laboratory practices and, therefore, the vast majority of candidate biomarkers fail to be substantiated in subsequent studies. Recognizing that validation is the point at which most biomarkers fail, our strategy is to reduce the attrition rate between discovery and clinical implementation by building validation into the discovery process. Biomarkers fail to validate for a number of reasons, which can be broadly classified into pre-analytical and analytical factors. Pre-analytical factors include study design that does not mimic actual clinical practice, inclusion of the wrong types of control individuals and demographic

bias (usually seen in studies in which samples are collected from a single institution). Analytical factors include poor control over laboratory protocols, inadequate randomization of study samples and instrumentation biases (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 and Overa, 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.

New Ovarian Cancer Indications

While our focus on supporting the commercialization of OVA1 is our primary priority, we also may extend our ovarian cancer franchise beyond OVA1, enabled by several factors:

- We received FDA clearance of a product improvement to OVA1, known as Overa, in March 2016;
- 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;
- We possess a large and growing portfolio of intellectual property, generated through collaborative research and licensing;
- We have 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
- Our 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.

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. In October 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union. We are targeting markets outside of the United States now that we have Overa cleared on the Roche cobas platform, which is available globally. In 2016, we signed our first contracts with distributors outside the United States so that we may begin marketing Overa and OVA1 outside the United States in 2017.

Approximately 9,125 OVA1 tests were performed in 2016 compared to 13,598 in 2015, with the decrease being attributed to account losses associated with the transition of accounts from Quest Diagnostics to ASPiRA LABS. In 2016, we continued to develop the market through experienced market development specialists, and customer account managers. As market awareness continues to build, these managers are focused on efforts that will have a positive impact on regional payers and create positive coverage decisions. They are working with local key opinion leaders and meeting with medical directors to discuss the clinical need, our technology assessment package and increasing experience and cases studies showing the positive outcomes utilizing OVA1.

There are still obstacles to overcome and significant milestones ahead. First, the average gynecologist will only see about 2 to 4 patients per month who may need our test, and additional effort will be required to establish a consistent ordering pattern.

Second, insurance coverage and patient bills are a concern to the physician and can disrupt the ordering pattern of a generalist who is supportive of OVA1.

Reimbursement

Because testing has transitioned from Quest Diagnostics to ASPiRA LABS, we assumed responsibility for billing third-party payers for OVA1. 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, client bill accounts and patients. Novitas Solutions, the Medicare contractor that had jurisdiction over claims submitted by Quest Diagnostics for OVA1, now covers and reimburses ASPiRA LABS for OVA1 as well. The local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. However, ASPiRA LABS has experienced difficulty in obtaining payment from Novitas Solutions for most claims submitted due to Novitas Solutions' administrative requirements. In October 2016, however, Novitas Solutions revised its administrative requirements for OVA1 reimbursement. We believe this change will greatly improve our ability to obtain reimbursement for OVA1 from Novitas Solutions.

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. In late 2016, OVA1 was included on the list of clinical diagnostic laboratory test procedure codes as one for which the CMS would require reporting of private payer rates as part of the implementation of Protecting Access to Medicare Act of 2014 ("PAMA"). Future Medicare pricing of OVA1 is expected to be based on the weighted median of final private payer rates from January through June 2016. New rates are scheduled to take effect on January 1, 2018. Currently ASPiRA LABS reimbursement has been established by the local Medicare Administrative Contractor for OVA1.

In July 2016, as part of our campaign to pursue managed care coverage agreements, we entered into contracts for payer coverage of OVA1 with Priority Health Managed Benefits, a Michigan healthcare insurance company, and Independent Medical Systems, a preferred provider organization based in Dallas, Texas. In August 2016, we announced a contract for payer coverage of OVA1 with Sutter Valley Medical Foundation (d/b/a Gould Medical Foundation), a California network provider. In September 2016, we announced a contract for payer coverage of OVA1 with CareFirst BlueCross BlueShield. In March 2017, we announced contracts for payer coverage of OVA1 with BlueCross BlueShield of Michigan and TriCare South and receipt of out-of-state provider status with Medi-Cal, California's Medicaid program.

New and innovative diagnostic tests often face reimbursement challenges that can affect adoption, including:

Coding

- We received an American Medical Association ("AMA") Current Procedural Terminology ("CPT") Category I code specific for OVA1, which was effective beginning January 1, 2013. Achieving the unique Category I CPT code # 81503 was a critical step in our commercialization process.
- We received a Proprietary Laboratory Analyses (PLA) code #0003U for Overa from the AMA's CPT® Editorial Panel effective January 1, 2017. This new code is included in the first set of PLA codes to be released by the AMA to support the implementation of Section 216 of PAMA, which replaces the current Medicare Clinical Laboratory Fee Schedule with a new fee schedule based upon laboratory-reported private payer rates. PLA codes are proprietary clinical laboratory analyses that can be either provided by a single ("sole-source") laboratory or licensed or marketed to multiple providing laboratories (e.g., cleared or approved by the FDA).

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 for our customers. We are using these claims to educate payers and create awareness about the medical necessity of our test.

Payer Coverage

- We have continued to focus ongoing efforts toward obtaining national coverage decisions. However, these decisions typically have a much longer lead time due to industry established processes and time frames. In most cases, these entail clinical and technical reviews that are performed on an annual basis.
- We have 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.

Fujirebio Diagnostics sells Risk of Ovarian Malignancy Algorithm ("ROMA"). 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. 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 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 the registered trademarks for *Vermillion, OVA1, Overa* and *OvaCalc* and a portfolio of owned, co-owned or licensed patents and patent applications. As of December 31, 2016, our clinical diagnostics patent portfolio included 19 issued United States patents, 11 pending United States patent applications, and numerous pending patent applications and issued patents outside the United States. These patents and patent applications fall into 25 patent families and are directed to diagnostic technologies.

Our research collaboration agreement with JHU expired on March 31, 2016. Collaboration costs under the JHU collaboration were $264,000 and $600,000 for the years ended December 31, 2016 and 2015, 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 $57,500. Other institutions and companies from which we hold options to license intellectual property related to biomarkers or are a co-inventor on applications include UCL, M.D. Anderson, UK, OSU, McGill University (Canada), Eastern Virginia Medical School, Aaron Diamond AIDS Research Center, UTMB, Goteborg University (Sweden), University of Kuopio (Finland), The Katholieke Universiteit Leuven (Belgium) and Rigshospitalet.

Manufacturing

We are the manufacturer of OVA1 and Overa. Components of OVA1 and Overa 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 and Overa. Only reagent lots determined by us as having met these specifications are permitted for use in OVA1 and Overa. Our principal suppliers are Roche Diagnostics Corporation and Siemens Healthcare Diagnostics, Inc.

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 and ASPiRA IVD are 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 received 510(k) clearance for Overa, our second-generation biomarker panel in March 2016.

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"). 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 passed an FDA inspection in 2016. However, we cannot ensure that we will pass any future 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 state agencies. As a medical device manufacturer, we are also required to register and list our products with the FDA. We are required to set forth and adhere to a quality policy and other regulations. In addition, we are required to comply with the

FDA's QSRs, which require that our devices be manufactured and records be maintained in a prescribed manner with respect to manufacturing, testing and control activities. Additionally, we may be subject to inspection by federal and state regulatory agencies. Non-compliance with these standards can result in, among other things, fines, injunctions, civil penalties, recalls, and total or partial suspension of production. Further, we are required to comply with FDA requirements for labeling and promotion. For example, the FDA prohibits cleared or approved devices from being promoted for uncleared or unapproved uses. Labeling and promotional activities are subject to scrutiny by the FDA, which prohibits the marketing of medical devices for unapproved uses. Additionally, the FDA requires us to perform certain post-marketing studies to verify or validate the clinical performance of FDA-cleared tests, as is permitted by their statutory authority. 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 2015, 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. On October 26, 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union.

Employees

As of December 31, 2016, we had 33 employees who are all full-time. 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 78738, 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 Investor Overview 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 Three, Suite 100
Austin, TX 78738

The information contained on our websites 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 described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition, 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 will be adversely affected.

We have experienced significant operating losses each year since our inception and we expect to incur a net loss for fiscal year 2017. Our losses have resulted principally from costs incurred in cost of revenue, research and development, sales and marketing, and general and administrative costs.

Prior to August 2015, all of our revenues were generated from sales of OVA1 tests performed by Quest Diagnostics. Pursuant to our March 2015 agreement with Quest Diagnostics, OVA1 testing in the United States for Quest Diagnostics customers was transitioned from Quest Diagnostics to ASPiRA LABS as of August 10, 2015. If we are unable to increase the volume of OVA1 sales, our business, results of operations and financial condition will be adversely affected.

In the past, a significant amount of our revenue was derived from Quest Diagnostics, and as testing services have been transitioned to ASPiRA LABS, there is no guarantee that we will be able to successfully market our test through additional channels, including ASPiRA LABS, in the future.

The majority of our revenue during 2015 was derived through our strategic partnership with Quest Diagnostics prior to transitioning OVA1 testing services for its customers to ASPiRA LABS. Prior to the transition, revenue generated from Quest Diagnostics was based on the number of OVA1 tests performed by Quest Diagnostics and the reimbursement rate received by Quest Diagnostics for those tests. We continue to depend on Quest Diagnostics for blood draw and logistics for a significant portion of our specimens under a contract through at least March 11, 2018. There is no guarantee that Quest Diagnostics will perform as expected, or provide a sufficient volume of OVA1 test samples to support our business, or extend the contract past the current expiration date. Due in part to this uncertainty, we plan to offer OVA1 through additional channels in the future, although there can be no assurance that we will be able to do so. In addition, as a result of the transition of OVA1 testing services from Quest Diagnostics to ASPiRA LABS, we have assumed responsibility for obtaining payment from third-party payers, whereas prior to the transition, Quest Diagnostics performed that task. Quest Diagnostics has more bargaining power with third-party payers than we do, and as a result, we may not be able to achieve reimbursement rates that are as high as those received by Quest Diagnostics. 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, there could be a material adverse effect on our business, results of operations and financial condition.

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.

In 2015, Quest Diagnostics largely transitioned OVA1 testing services for its customers to ASPiRA LABS. As a result of the transition, we have assumed responsibility for obtaining payment from third-party payers, whereas prior to the transition, Quest Diagnostics performed that task. Accordingly, our future revenues will be dependent upon third-party reimbursement payments to ASPiRA LABS. 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 Overa 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 Multianalyte Assays with Algorithmic Analyses, such as our OVA1 and Overa tests. There is no guarantee that CMS will issue the codes and rates, that the codes will continue to 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 and Overa are largely out of our control. We have experienced volatility in the coverage and reimbursement of OVA1 due to contract negotiation with third-party payers and implementation requirements and the reimbursement amounts we have received from third-party payers varies from payer to payer, and, in some cases, the variation is material.

Third-party payers, including private insurance companies as well as government payers such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization of diagnostic tests such as OVA1. From time to time, Congress has considered and

implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in third-party payer reimbursement rates may occur in the future. Reductions in the price at which OVA1 and Overa is reimbursed could have a material adverse effect on our business, results of operations and financial condition. If we are unable to establish and maintain broad coverage and reimbursement for OVA1 and Overa 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 and Overa both within and outside the United States, and there is no assurance that we will be able to do so successfully.

We received FDA clearance for Overa in March 2016 and launched Overa with customers on a targeted basis in October 2016. Overa is intended to maintain our product's high sensitivity while improving specificity. Though we plan to leverage off our existing infrastructure for OVA1, including ASPiRA LABS, there can be no assurance that we will be successfully able to commercialize Overa in the United States, or that we will be able to obtain reimbursement for Overa from third-party payers at the same rate as OVA1. If we are unable to successfully commercialize Overa, the results of our operations could be adversely affected.

Additionally, in 2015 and 2016, all of our product revenue was generated in the United States. In 2016, we entered into our initial contracts with customers and other distributors and partners outside the United States, so that we may begin directly or indirectly marketing and selling Overa outside the United States in 2017. 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, while we registered the CE mark and in October 2015 obtained clearance to market Overa in the European Union, we may be prohibited in the future from directly or indirectly marketing or selling Overa in the European Union or various other 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 or Overa 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 and Overa outside the United States, there are risks inherent in conducting business internationally, including the following:

- data privacy laws that may apply to the transmission of any clients' and employees' data to the United States;
- import/export sanctions and restrictions;
- compliance with applicable anti-corruption laws;
- difficulties in managing international distributors;
- accounting, tax and legal complexities arising from international operations;
- potential difficulties in transferring funds generated overseas to the United States in a tax efficient manner; and
- political 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 and Overa 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. In addition, our efforts to develop diagnostic tests for endometriosis and PCOS are in the discovery phase, and future pre-clinical or clinical studies may not support our early data. 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 and Overa, 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, Overa 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 or Overa 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 and Overa provide significant improvement over current clinical practices, our ability to commercialize OVA1 and Overa will 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 Laboratories have publicly disclosed that they have been or are currently working on ovarian cancer diagnostic assays. Academic institutions periodically report new findings in ovarian cancer diagnostics that may have commercial value. Our failure to compete with any competitive diagnostic assay if and when commercialized could adversely affect our business, financial condition and results of operations.

We have priced OVA1 and Overa 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 and Overa 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 Overa in March 2016 and 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. While the OVA1 post-market study has been completed and closed with the FDA, Overa also has a post-market surveillance requirement which is under discussion with the FDA. 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.

If 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. For instance, we are subject to a number of FDA requirements, including compliance with the FDA's Quality System Regulations "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. We will need to undertake steps to maintain our operations in line with the FDA's QSR requirements. Some components of OVA1 and Overa are manufactured by other companies and we are required to ensure that, to the extent that we incorporate those components into our finished OVA1 or Overa test, we use those components in compliance with QSR. Any failure to do so would have an adverse effect on our ability to commercialize OVA1 or Overa. Our suppliers' manufacturing facilities, since they manufacture finished kits that we use in OVA1 and Overa, are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. Our facility also is subject to FDA inspection. 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 and Overa.

The commercialization of our OVA1 and Overa tests depend on the supply of five different immunoassay kits from third-party manufacturers that run on automated instruments. Failure by any of these manufacturers to produce kits that pass our 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 or Overa 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 or Overa design. Likewise, discontinuation or failure to support or service the instruments may pose risk to ongoing operations.

Effective December 2014, one 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. Overa consolidates the five OVA1 immunoassays onto a single mainstream automated platform and substitutes a new immunoassay component kit for the discontinuing kit as a mitigating action. Although we received a 510(k) clearance from the FDA for Overa in March 2016, there can be no assurances that there will not be future disruptions in our supply chain. Any resulting disruption to our supply of OVA1 or Overa would 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 Johns Hopkins University School of Medicine and the University of Texas M.D. Anderson Cancer Center. In some cases, our collaborators own the entire right to the biomarkers. In other cases, we co-own the biomarkers with our collaborators. If, for some reason, we lose our license to biomarkers owned entirely by our collaborators, we may not be able to use those biomarkers in diagnostic tests. If we lose our exclusive license to biomarkers co-owned by us and our collaborators, our collaborators may license their share of the intellectual property to a third party that may compete with us in offering diagnostic tests, which would materially adversely affect our business, results of operations and financial condition.

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

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

If third parties engage in activities that infringe on our proprietary rights, we may incur significant costs in asserting our rights, 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. If we are found liable, we may be subject to monetary damages or an injunction prohibiting us from using the technology. We may also be required to obtain licenses under patents owned by third parties and such licenses may not be available to us on commercially reasonable terms, if at all.

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

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

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

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

The testing, manufacturing and marketing of medical diagnostic tests entail an inherent risk of product liability claims. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. We will need to increase our amount of insurance coverage in the future if we are successful at introducing new diagnostic products, and this will increase our costs. If we are held liable for a claim or for damages exceeding the limit 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.

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.

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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA") requires each medical device manufacturer to pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices (currently under a moratorium until December 31, 2017). 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. The Protecting Access to Medicare Act of 2014, which halted certain reductions in payment mandated by the PPACA as well as certain CMS policies, 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 as early as 2016. CMS also issued various regulations and guidance generally effective in 2014 that limited reimbursement for clinical laboratory tests as a general matter, but permitted the continued ability for CMS to pay for Multianalyte Assays with Algorithmic Analyses 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.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump has also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of burdensome provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold. Any changes could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted that reduced payments to Medicare providers. The ultimate implementation of any healthcare reform legislation and any new laws and regulations, and its impact on us, is impossible to predict. Any significant reforms made to the healthcare system in the United States, or in other jurisdictions, may have an adverse effect on our business, financial condition and results of operations.

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

We are subject to various international, federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, the recycling and treatment of electrical and electronic equipment, and emissions and discharges into the environment. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We are also subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs to remediate hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, as well as incur liability to third parties affected by such contamination. The presence of, or failure to remediate properly, such substances could adversely affect the value and the ability to transfer or encumber such property.

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 clinical laboratory, ASPiRA LABS, involved 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.

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 revenue in excess of expenses, and we may not achieve profitability from ASPiRA LABS in the foreseeable future, if at all. If we are unable to generate sufficient revenues to 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 operation 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.

ASPiRA LABS holds a CLIA Certificate of Accreditation and a state laboratory license in California, Florida, Maryland, New York, Pennsylvania and Rhode Island. This allows the lab to process OVA1 on a national basis. 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 suspension or revocation of our CLIA certification or state licenses. If our CLIA certification or state licenses are 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 finalizes its October 2014 draft guidance documents that outline the FDA's proposal to actively regulate LDTs, we may need to obtain a 510(k) clearance or pre-market approval for our future LDTs, and there is no guarantee that we would ever procure the needed FDA clearance or approval. We also would need to comply with ongoing regulatory requirements.

We intend to develop and perform LDTs at ASPiRA LABS in the future. The FDA has historically exercised enforcement discretion and not required approvals or clearances for LDTs. However, in October 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs.

According to the draft guidance documents, all laboratories with LDTs—except for those only performing forensic testing or certain LDTs for transplantation—would need to comply with some basic statutory requirements, regardless of the risks of the tests, including adverse event reporting, corrections and removals reporting and registration and listing or notification.

In addition, "high" and "moderate" risk tests not subject to an exemption will need to be the subject of a PMA or 510(k) submitted to the FDA in a phased-in manner. High-risk tests are those that are classified as Class III devices. Within those high-risk devices, the FDA identifies the "highest risk devices" as (1) LDTs with the same intended use as an approved or cleared companion diagnostic; (2) LDTs with the same intended use as an FDA-approved Class III device; and (3) certain LDTs for determining safety and effectiveness of blood or blood products. Moderate-risk tests are those that are classified as Class II devices. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and, if so, how the final framework might differ from the proposal. In addition, the new regulatory requirements are proposed to be phased in consistent with the schedule set forth in the guidance documents for tests that are on the market at the time the guidance documents are finalized.

Legislative proposals addressing the FDA's oversight of LDTs have been previously introduced, and we expect that new legislative proposals will be introduced from time to time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate LDTs as medical devices is difficult to predict.

Even before the FDA finalizes such guidance documents, 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, results of operations and financial condition 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. Obtaining FDA clearance or approval for diagnostics can be expensive, time consuming and uncertain, and for higher-risk devices generally takes several years and requires detailed and comprehensive scientific and clinical data. In addition, medical devices are subject to ongoing FDA obligations and continued regulatory oversight and review. 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.

ASPiRA IVD is a new business venture with no operating history and may subject us to additional risks.

As of the date of the filing of this Annual Report on Form 10-K with the SEC, we have limited operating results with respect to providing IVD trial services to third parties through ASPiRA IVD, and, therefore, we do not have an operating history upon which you can evaluate this new line of business or its prospects. Cash in-flows from our new IVD trial services business may not meet expectations, and ASPiRA IVD's prospects must be considered in light of the risks and uncertainties inherent in entering into a new line of business, including:

- the potential diversion of management's attention and other resources away from our existing business;
- our relative inexperience with respect to offering IVD trial services;
- external factors, such as compliance with regulations, competitive alternatives and shifting market preferences;

- the need for additional capital and other resources to expand our IVD trial services business; and
- its impact on our system of internal controls.

Failure to successfully manage these risks in the development and implementation of ASPiRA IVD's trial services business could have an adverse effect on our business, financial condition and results of operations.

The success of ASPiRA IVD depends on our ability to generate and maintain new business awards and contracts, and if we fail to do so, it could adversely affect our business, financial condition and results of operations.

The success of ASPiRA IVD depends on our ability to generate new business awards and new customers and contracts for clinical development services and other services. The time between when a study is awarded and when it goes to contract can be several months, and prior to a new business award going to contract, our potential customers will be able to cancel the award without notice. We expect that, once an award goes to contract, the majority of our customers will be able to terminate the contract with 30 days' notice. Our IVD contracts may be delayed or terminated by our customers or reduced in scope for a variety of reasons beyond our control, including the following:

- decisions to forego or terminate a particular trial;
- budgetary limits or changing priorities;
- actions by regulatory authorities;
- production problems resulting in shortages of the drug or device being tested;
- failure of products being tested to satisfy safety requirements or efficacy criteria;
- unexpected or undesired clinical results for products;
- insufficient patient enrollment in a trial;
- insufficient principal investigatory recruitment;
- shift of business to a competitor or internal resources; or
- product withdrawal following market launch.

As a result, we expect that contract terminations, delays and modifications will be a regular part of ASPiRA IVD's business. In the event of termination, ASPiRA IVD's contracts will provide for fees for winding down the project, which include both fees incurred and actual and non-cancellable expenditures, and may also include a fee to cover a percentage of the remaining professional fees on the project. These fees may not be sufficient for us to maintain our margins, and termination may result in lower resource utilization rates and therefore lower operating margins. Cancellation of a clinical trial may also result in the unwillingness or inability of our customers to satisfy certain associated accounts receivable. Additionally, a change in the timing of a new business award could affect the period over which we recognize revenue and reduce our revenue in any one quarter. If ASPiRA IVD is unable to generate new business awards on a timely basis and subsequently enter into and maintain contracts for such awards, our business, financial condition and results of operations could be adversely affected.

Operating results for ASPiRA IVD may fluctuate significantly between fiscal quarters, which may adversely affect the market price of our stock.

Operating results for ASPiRA IVD may fluctuate significantly from quarter to quarter and may be influenced by a variety of factors, such as:

- timing of contract amendments for changes in scope that could affect the value of a contract and potentially impact the amount of net new business awards and net service revenues from quarter to quarter;
- commencement, completion, execution, postponement or termination of large contracts;
- contract terms for the recognition of revenue milestones;
- progress of ongoing contracts and retention of customers;
- changes in the mix of services we are contracted to perform; and
- potential customer disputes, penalties, or other issues that may impact the revenue we are able to recognize or the collectability of our related accounts receivable.

ASPiRA IVD's operating results for any particular quarter will not necessarily be a meaningful indicator of its future results. The resulting fluctuations in the Company's quarterly operating results could negatively affect the market price and liquidity of shares of our common stock.

If we underprice our IVD contracts, overrun our IVD cost estimates or fail to receive approval for or experience delays in documentation of IVD change orders, it could adversely affect our business, financial condition and results of operations.

We plan to price our IVD contracts based on assumptions regarding the scope of work required and cost to complete the work. We will bear the financial risk if we initially underprice our contracts or otherwise overrun our cost estimates, which could adversely affect ASPiRA IVD's cash flows and financial performance. In addition, we anticipate that contracts with ASPiRA IVD's customers will be subject to change orders, which may occur when the scope of work we perform needs to be modified from that originally contemplated in our customer contracts. This can occur, for example, when there is a change in a key study assumption or parameter or a significant change in timing. We may be unable to successfully negotiate changes in scope or change orders on a timely basis or at all, which may require us to incur cost outlays ahead of the receipt of any additional revenue. In addition, under generally accepted accounting principles in the United States we will not be able to recognize additional revenue anticipated from change orders until appropriate documentation is received by us from the customer authorizing the change. However, if we incur additional expense in anticipation of receipt of that documentation, we will need to recognize the expense as incurred. Any of the foregoing could adversely affect our business, financial condition and results of operations.

The operation of ASPiRA IVD and ASPiRA LABS depend on the effectiveness and availability of our information systems, including the information systems we use to provide services to our customers and to store employee data, and failures of these systems, including in connection with cyber-attacks, may materially limit our operations or have an adverse effect on our reputation.

The information systems we use for our IVD trial business are comprised of systems we have purchased or developed, our legacy information systems and, increasingly, web-enabled and other integrated information systems. In using these information systems, we may rely on third-party vendors to provide hosting services, where our infrastructure is dependent upon the reliability of their underlying platforms, facilities and communications systems. We also plan to utilize integrated information systems that we provide customers access to or install for our customers in conjunction with our delivery of services.

As the breadth and complexity of ASPiRA IVD's information systems grows, we will increasingly be exposed to the risks inherent in maintaining the stability of our legacy systems due to prior customization, attrition of employees or vendors involved in their development, and obsolescence of the underlying technology as well as risks from the increasing number and scope of external data breaches on companies generally. Because certain customers and clinical trials may be dependent upon these legacy systems, we will also face an increased level of embedded risk in maintaining the legacy systems and limited options to mitigate such risk. We are also exposed to risks associated with the availability of all of our information systems, including:

- disruption, impairment or failure of data centers, telecommunications facilities or other key infrastructure platforms, including those maintained by third-party vendors;
- security breaches of, cyber-attacks on and other failures or malfunctions in our internal systems, including our employee data and communications, critical application systems and their associated hardware; and
- excessive costs, excessive delays and other deficiencies in systems development and deployment.

The materialization of any of these risks may impede the processing of data, the delivery of databases and services, and the day-to-day management of our IVD trial business and could result in the corruption, loss or unauthorized disclosure of proprietary, confidential or other data. While we have disaster recovery plans in place in line with applicable regulations and industry standards, they might not adequately protect us in the event of a system failure. Despite any precautions we take, damage from fire, floods, hurricanes, the outbreak or escalation of war, acts of terrorism, power loss, telecommunications failures, computer viruses, break-ins and similar events at our various computer facilities or those of our third-party vendors could result in interruptions in the flow of data to us and from us to our customers. Corruption or loss of data may result in the need to repeat a trial at no cost to the customer, but at significant cost to us, the termination of a contract or damage to our reputation. As our business continues its efforts to expand globally, these types of risks may be further increased by instability in the geopolitical climate of certain regions, underdeveloped and less stable utilities and communications infrastructure, and other local and regional factors. Additionally, significant delays in system enhancements or inadequate performance of new or upgraded systems could damage our reputation and harm our business. Although we carry property and business interruption insurance which we believe is customary for our industry, our coverage might not be adequate to compensate us for all losses that may occur.

Unauthorized disclosure of sensitive or confidential data, whether through systems failure or employee negligence, cyber-attacks, fraud or misappropriation, could damage our reputation and cause us to lose customers and, to the extent any such unauthorized disclosure compromises the privacy and security of individually identifiable health information, could also cause us to face sanctions and fines under the Federal Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act of 2009. Similarly, we have been and expect that we will continue to be subject to attempts to gain unauthorized access to or through our information systems or those we internally or externally develop for our customers, including a cyber-attack by computer programmers and hackers who may develop and deploy viruses, worms or other malicious software programs, process breakdowns, denial-of-service attacks, malicious social engineering or other malicious

activities, or any combination of the foregoing. In addition, we may be susceptible to physical or computer-based attacks by terrorists or hackers due to ASPiRA IVD's role in the contract research organization industry. These concerns about security are increased when information is transmitted over the Internet. Threats include cyber-attacks such as computer viruses, worms or other destructive or disruptive software, and any of these could result in a degradation or disruption of our services or damage to our properties, equipment and data. They could also compromise data security. If such attacks are not detected immediately, their effect could be compounded. These same risks also apply to ASPiRA LABS. Successful attacks could result in negative publicity, significant remediation and recovery costs, legal liability and damage to our reputation and could have an adverse effect on our business, financial condition and results of operations.

If ASPiRA IVD fails to perform its services in accordance with contractual requirements, regulatory standards and ethical considerations, we could be subject to significant costs or liability and our business or reputation could be harmed.

We anticipate that ASPiRA IVD will contract with biopharmaceutical companies to perform a wide range of services to assist them in bringing new drugs to market. Our IVD trial services will include monitoring clinical trials, data and laboratory analysis, patient recruitment and other related services. Such services are complex and subject to contractual requirements, regulatory standards and ethical considerations. For example, ASPiRA IVD will be required to adhere to applicable regulatory requirements such as the FDA's Quality System Regulations, CLIA, and current Good Clinical Practices, which govern, among other things, the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. If ASPiRA IVD fails to perform its services in accordance with these requirements, regulatory authorities may take action against us or our customers. Such actions may include sanctions (e.g., injunctions or the failure of such regulatory authorities to grant marketing approval of products), imposition of clinical holds or delays, suspension or withdrawal of approvals, rejection of data collected in studies conducted by ASPiRA IVD, license revocation, product seizures or recalls, operational restrictions, civil or criminal penalties or prosecutions, damages or fines. Additionally, there is a risk that actions by regulatory authorities, if they result in significant inspectional observations or other measures, could harm our reputation and cause customers not to award ASPiRA IVD future contracts or to cancel existing contracts. Any such action could have an adverse effect on our business, financial condition and results of operations.

Risks Related to Owning Our Stock

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

The liquidity and trading volume of our common stock has at times been low in the past and may again be low in the future. If the liquidity and trading volume of our common stock is low, this could adversely impact the trading price of our shares, our ability to issue stock and our stockholders' ability to obtain liquidity in their shares. The issuance of common stock by us in May 2013 and subsequent warrant exercise in December 2013, and the issuance of common stock by us in December 2014, July 2015 and February 2017 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 Schedules 13D, and 13G, as amended, filed as recent as February 28, 2017, five persons beneficially owned approximately 68% of our outstanding shares of common stock, 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 or Overa;
- 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;
- our ability to continue as a going concern;
- 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 in May 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.

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.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of the exercise of common stock warrants, public or private equity offerings, debt financings, collaborations, licensing arrangements, grants and government funding and strategic alliances. To the extent that we raise additional capital through the sale of equity or convertible debt, such financing may be dilutive to stockholders. Debt financing, if available, may involve restrictive covenants and potential dilution to stockholders. Furthermore, a perception that future sales of our common stock in the public market are likely to occur could affect prevailing trading prices of our common stock.

As of December 31, 2016, we had 52,328,492 shares of our common stock outstanding and 2,989,760 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 3,451,073 shares of our common stock that were subject to outstanding options. In addition, as of December 31, 2016, warrants to purchase 4,166,659 shares of our common stock were outstanding. These warrants are exercisable at the election of the holders thereof at an average exercise price of $2.00 per share.

On February 17, 2017, Vermillion completed a private placement pursuant to which certain investors purchased 3,747,125 shares of Vermillion common stock at a price of $1.40 per share. Vermillion also issued warrants to purchase shares of common stock at a price of $0.125 per warrant share in the private placement. The warrants are exercisable for 2,810,338 shares of Vermillion common stock at $1.80 per share.

The exercise of all or a portion of our outstanding options and warrants will dilute the ownership interests of our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal facility is located in Austin, Texas. The following chart indicates the facilities 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	4,218 sq. ft.	ASPiRA LABS facility, research and development, clinical and regulatory, sales and administrative offices	May 31, 2017
Trumbull, Connecticut	10,681 sq. ft.	Administrative offices and ASPiRA IVD laboratory facility	June 2021

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock is traded on the NASDAQ Capital Market under the symbol "VRML."

On March 8, 2017, there were 98 registered holders of record of our common stock. The closing price of our common stock on March 24, 2017 was $2.14.

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

	2016		2015	
	High	Low	High	Low
First Quarter	$ 1.94	$ 1.00	$ 2.35	$ 1.50
Second Quarter	1.58	1.00	2.50	1.68
Third Quarter	1.50	0.92	2.29	1.47
Fourth Quarter	1.33	0.76	2.20	1.63

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.

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 Amended and Restated 2010 Stock Incentive Plan, as amended (the "2010 Plan").

2000 Plan. The authority of Vermillion's 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, 2016, options to purchase 21,050 shares of Vermillion's common stock remained outstanding under the 2000 Plan.

2010 Plan. The 2010 Plan is administered by the Compensation Committee of Vermillion's 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, unrestricted shares, deferred share units, performance and cash-settled awards, and dividend equivalent rights. We are authorized to issue up to 8,122,983 shares of Vermillion's common stock under the 2010 Plan, subject to adjustment as provided in the 2010 Plan. At December 31, 2016, options to purchase 3,430,023 shares of common stock remained outstanding under the 2010 Plan.

The number of shares of Vermillion's 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, 2016, 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	3,451,073 (1)	$ 1.70 (2)	2,989,760 (3)
Equity compensation plans not approved by security holders	-	-	-
Total	3,451,073		2,989,760

(1) Includes outstanding stock options for 21,050 shares of our common stock under the 2000 Plan and 3,430,023 shares of our common stock under the 2010 Plan.

(2) Includes the weighted average stock price for outstanding stock options of $3.22 under the 2000 Plan and $1.69 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 CONDITION AND RESULTS OF OPERATIONS

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

Overview

Our vision is to drive the advancement of women's health by providing innovative methods to detect, monitor and manage the treatment of both benign and malignant gynecologic disease, with our primary focus being diseases of the female pelvic cavity.

We have expanded our corporate strategy with the goal of transforming the Company 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 is being deployed in three phases. The three phases are a rebuild phase, which was completed in the third quarter of 2015, a transformation phase, which is ongoing, and a market expansion and growth phase, which we expect to begin in 2017.

During the first phase, we expanded our leadership team by hiring several new senior leaders including 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 completed the process of obtaining licensure of ASPiRA LABS in all of the states that require licenses, are in the process of establishing our own payer coverage for OVA1, Multivariate Index Assay (MIA), and launched a second-generation OVA1 test, trademarked Overa, Multivariate Index Assay, 2nd Generation (MIA2G), on a targeted basis. In the third phase, we plan to fully commercialize Overa by utilizing the full national licensure of ASPiRA LABS, select distributor laboratories, managed care coverage in select markets, our sales force and existing customer base. Unlike OVA1, Overa uses a global testing platform, which will allow Overa to be deployed internationally. We initiated the targeted launch of Overa in October 2016 with two key accounts converting from OVA1 to Overa. In October 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union. We also plan to develop an LDT product series, which we refer to internally as OvaX. We anticipate that OvaX will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value.

In February 2016, we adopted a plan to streamline our organization. We restructured headcount and other expenses targeting an approximately 20% reduction in operating expenses in 2016, as compared to operating expenses in 2015.

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 biomarkers, other modalities 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 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.

Business: Our initial product, OVA1, is a blood test designed to, in addition to a physician's clinical assessment of a woman with a pelvic mass, identify women who are at high risk of having a malignant ovarian tumor prior to planned surgery. The FDA cleared OVA1 in September 2009, and we commercially launched OVA1 in March 2010. We have launched on a targeted basis a second-generation biomarker panel known as Overa, which is intended to maintain our product's high sensitivity while improving specificity. We received FDA clearance for Overa on March 18, 2016. Overa uses the Roche cobas 6000 platform.

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 and disease. ASPiRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based diagnostic algorithm to aid in clinical decision making and advance personalized treatment plans. The lab currently processes our OVA1 and Overa tests, and we plan to expand the testing to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPiRA LABS. ASPiRA LABS holds a CLIA Certificate of Registration and a state laboratory license in California, Florida, Maryland, New York, Pennsylvania and Rhode Island. This allows the lab to process OVA1 and Overa on a national basis. The CMS issued a provider number to ASPiRA LABS in March 2015.

In 2016, we created a new service within the ASPiRA channel strategy, "an ASPiRA IVD Services Program". In April 2016, we formed ASPiRA IVD to offer IVD trial services to third-party customers. ASPiRA IVD is a specialized laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. ASPiRA IVD was built around a core of laboratory expertise and an FDA-compliant quality system, and strives to deliver accurate and

reliable results to its third-party customers suitable for FDA submission. ASPiRA IVD received a CLIA laboratory license in June 2016 and commenced operations in the second quarter of 2016.

In this ASPiRA IVD program, we plan to leverage our existing infrastructure and enhance our pipeline of future technologies by fostering relationships with IVD companies who are developing new diagnostics including companion diagnostics platforms. We believe this plan will allow us to continue to be innovative in evaluating potential diagnostics. Our goal with the addition of this line of business is to invest in our short-term and long-term enterprise value while leveraging specimen bank, database, FDA experience, laboratory informatics and operating efficiency.

Strategy: We are focused on the execution of five core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to build long-term value for our investors:

- Maximizing the existing OVA1 opportunity in the United States by taking the lead in payer coverage and commercialization of OVA1. This strategy included the launch of a CLIA certified clinical laboratory, ASPiRA LABS, in June 2014;

- Improving OVA1 specificity and expanding the distribution platform by launching Overa, a next generation biomarker panel, on a targeted basis while building the clinical utility and health economics foundation of both OVA1 and Overa, which we believe may allow for better domestic market penetration and international expansion (FDA clearance for Overa was received on March 18, 2016);

- Leveraging our existing database and specimen bank while building the largest specimen and data repository of gynecologic pelvic mass patients worldwide;

- Expanding our product offerings to additional pelvic disease conditions such as endometriosis and polycystic ovarian syndrome (PCOS) 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; and

- Expanding our customer offerings with the launch of our ASPiRA IVD laboratory services.

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.

OVA1 and Overa address a clear clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 and Overa are qualitative serum tests that utilize 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 or Overa 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 or Overa 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 May 2016 we entered into our first international distribution agreement for Overa. Pursuant to this agreement, Bio-Medical Science Co., Ltd. has the right to market and distribute Overa on an exclusive basis in South Korea. Subsequently, we executed exclusive international distribution agreements for Overa with Pro-Genetics LTD in Israel and MacroHealth, Inc. in the Philippines. The MacroHealth agreement is our first decentralized international agreement with Overa specimen testing to be performed in the Philippines.

In July 2016, as part of our campaign to pursue managed care coverage agreements, we entered into contracts for payer coverage of OVA1 with Priority Health Managed Benefits, a Michigan healthcare insurance company, and Independent Medical Systems, a preferred provider organization based in Dallas, Texas. In August 2016, we announced a contract for payer coverage of OVA1 with Sutter Valley Medical Foundation (d/b/a Gould Medical Foundation), a California network provider. In September 2016, we announced a contract for payer coverage of OVA1 with CareFirst BlueCross BlueShield. In March 2017, we announced contracts

for payer coverage of OVA1 with BlueCross BlueShield of Michigan and TriCare South and receipt of out-of-state provider status with Medi-Cal, California's Medicaid program.

In October 2016, we launched our pelvic mass specimen and data repository and began the collection of patient consents under Institutional Review Board ("IRB") for collection and cataloguing of serum samples for future research purposes.

In November 2016, The American College of Obstetricians and Gynecologists ("ACOG") issued Practice Bulletin Number 174 which included OVA1 as a "Multivariate Index Assay". This bulletin outlines ACOG's "new" clinical management guidelines for adnexal mass management.

These new clinical management guidelines replace the July 2007 version, Practice Bulletin Number 83. Practice Bulletins summarize current information on techniques and clinical management issues for the practice of obstetrics and gynecology. Practice Bulletins are evidence-based documents, and recommendations are based on the evidence. This is also the only clinical management tool used for adnexal masses. Guidelines do not exist for adnexal masses, only Practice Bulletins. Guidelines do exist, however, for ovarian cancer management.

The Practice Bulletin recommends that obstetricians and gynecologists evaluating women with adnexal masses who do not meet Level A criteria of a low risk transvaginal ultrasound should proceed with Level B clinical guidelines. Level B guidelines state that the physician may use risk assessment tools such as existing CA125 technology or OVA1 as listed in the bulletin. Based on this, OVA1 has now achieved parity with CA125 as a Level B recommendation for the management of adnexal masses, but OVA1 is the only recommended Level B tool *that has FDA clearance for use* assessing ovarian cancer risk in women of all stages, ages, and cancer types..

In December 2016, we received an FDA Clarification Letter regarding OVA1 and Overa. This letter was in reference to the September 7, 2016 FDA Safety Communication advising women and their physicians against the use of ovarian cancer screening tests for asymptomatic women.

In order to avoid any confusion as well as to document the FDA position on OVA1 and Overa, Jeffrey Shuren, M.D, J.D, Director for the Center for Devices and Radiological Health at the FDA, sent a letter to Vermillion, dated December 21, 2016. In the letter, Dr. Shuren stated, "We agree that this safety communication does not apply to Vermillion's FDA-cleared tests, OVA1 (MIA) and Overa (MIA2G), which are not screening tests for ovarian cancer."

"FDA cleared OVA1 (MIA) and Overa (MIA2G) as aids to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The intended uses of the two assays are the same—to help physicians more reliably identify which patients would benefit from consultation with or referral to a gynecologic oncologist. OVA1 (MIA) and Overa (MIA2G) are indicated for women who present with an adnexal mass."

In March 2015, we entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Vermillion's wholly-owned subsidiary, ASPiRA LABS, as of August 10, 2015. Pursuant to this agreement, as amended as of March 11, 2017, Quest Diagnostics is continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing through at least March 11, 2018 in exchange for a market value fee. Per the terms of the new commercial agreement, we will not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers.

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 critical 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 (through August 2015) and ASPiRA LABS. The Company derives product revenue from sales of Overa through ASPiRA LABS.

The Company has adopted ASC 954-605, *Health Care Entities—Revenue Recognition,* as revenue from laboratory services has become significant to the Company. The Company's product revenue is generated by performing diagnostic services using its OVA1 and Overa tests, and the service is completed upon the delivery of test results to the prescribing physician. The Company recognizes revenue related to billings for Medicare and commercial payers on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be realized can be estimated. Until a contract has been negotiated with a commercial payer or governmental program, the OVA1 and Overa tests may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with the Company that commit them to pay any portion of the cost of the tests in the event that their insurance declines to reimburse the Company. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment from the patient, the related revenue is only recognized upon cash receipt.

Estimates of amounts that the Company will ultimately realize require significant judgment by management. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and the Company may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with the patient's health plan. Some payers may not cover the OVA1 or Overa test as ordered by the prescribing physician under their reimbursement policies. The Company pursues reimbursement from such patients on a case-by-case basis. In the absence of contracted reimbursement coverage or the ability to estimate the amount that will ultimately be realized for the Company's services, revenue is recognized when cash is received.

License Revenue. Under the terms of our former secured line of credit with Quest Diagnostics, portions of the borrowed principal amounts were to be forgiven upon our achievement of certain milestones relating to the development, regulatory approval and commercialization of certain diagnostic tests. We accounted for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest Diagnostics received upon commercialization of an approved diagnostic test as we did not have a sufficient history of product sales that provided a reasonable basis for estimating future product sales. Through December 31, 2014, we recognized 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 Diagnostics as part of the March 2015 agreement, and thus the remaining balance of deferred license revenue totaling $316,000 was recognized in the first quarter of 2015.

Service Revenue. The Company's service revenue is generated by performing IVD trial services for third-party customers. In accordance with SEC Staff Accounting Bulletin Topic 13, service revenue is recognized when the following revenue recognition criteria are met: (1) persuasive evidence of 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.

Revenue recognized when cash is received and on an accrual basis for three months and the year ended December 31, 2016 and 2015 was as follows:

	Three Months Ended December 31,		Year Ended December 31,	
(in thousands)	**2016**	**2015**	**2016**	**2015**
Quest Diagnostics	$ -	$ 3	$ -	$ 1,285
Cash basis	487	252	1,720	386
Accrual basis	193	106	600	190
IVD trial services (accrual basis)	125	-	322	-
Total	$ 805	$ 361	$ 2,642	$ 1,861

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 the fair value of stock options using a Black-Scholes option valuation model. This model requires the

input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. We use the straight-line method to amortize the fair value over the vesting period of the award. These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore are subject to management's judgment.

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

Contingencies

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

Income Taxes

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

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

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

Liquidity

In July 2015 the Company completed the sale of 9,602,500 shares of Vermillion common stock, at a price to the public of $1.96 per share, including 1,252,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in an underwritten public offering at a price of $1.96 per share. Net proceeds from the offering were approximately $17,495,000 after deducting underwriting discounts and offering expenses.

On March 22, 2016, we entered into an agreement (the "Loan Agreement") pursuant to which we may borrow up to $4,000,000 from the DECD. Proceeds from the loan were utilized primarily to fund the build-out, information technology infrastructure and other costs related to our Trumbull, Connecticut facility and operations. The loan bears interest at a fixed rate of 2.0% per annum and requires equal monthly payments of principal and interest until maturity, which occurs on April 15, 2026. As security for the loan, we have granted the DECD a blanket security interest in our personal and intellectual property. The DECD's security interest in our intellectual property may be subordinated to a qualified institutional lender. Under the terms of the agreement, we may be eligible for forgiveness of up to $2,000,000 of the principal amount of the loan if we achieve certain job creation and retention milestones measured by March 1, 2018. If we are unable to meet these job creation milestones within the allotted timeframe or do not maintain our Connecticut operations for a period of 10 years, the DECD may require early repayment of a portion or all of the loan depending on job attainment as compared to the required amount.

An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The Loan Agreement provides that the remaining $2,000,000 will be disbursed if and when the Company achieves certain future milestones.

On February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased 3,747,125 shares of Vermillion common stock at a price of $1.40 per share. Vermillion also issued warrants to purchase shares of common stock at a price of $0.125 per warrant share in the private placement. Net proceeds of the private placement were approximately $5,100,000 after deducting offering expenses. The warrants are exercisable for 2,810,338 shares of Vermillion common stock at $1.80 per share.

The warrants may be exercised from time to time beginning August 17, 2017 and expire on the fifth anniversary of the date of issuance or, if earlier, five business days after Vermillion delivers notice that the closing price per share of its common stock exceeded the exercise price for 20 consecutive trading days during the exercise period.

We have incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately $385,556,000 at December 31, 2016. The Company expects to incur a net loss in 2017 as well. 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 exercise of common stock warrants, (*e.g.*, the warrants to purchase 4,166,659 shares of Vermillion common stock at $2.00 per share, which warrants were issued in December 2014 and expire on December 23, 2017), public and private equity offerings, debt financing, collaborations, licensing arrangements, grants and government funding and strategic alliances. 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 Company's 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 and ASPiRA IVD sales to be the Company's only material, recurring source of cash in 2017.

In connection with a private placement offering of common stock and warrants we completed in May 2013, we entered into a stockholders agreement which, among other things, gives two of the primary investors in that offering the right to participate in any future equity offerings by the Company on the same price and terms as other investors. In addition, the stockholders agreement prohibits us from taking certain material actions without the consent of at least one of the two primary investors in that offering. These material actions include:

- Making any acquisition with a value greater than $2 million;
- 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;
- Taking any action that would result in a change in control of the Company or an insolvency event; and
- 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.

The foregoing 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, that were purchased at the closing of the 2013 private placement.

Recent Accounting Pronouncements

The information set forth in Note 2 to our consolidated financial statements contained in Part II, Item 8, "Financial Statements and Supplementary Data," of this Annual Report on Form 10-K is hereby incorporated herein by reference.

Results of Operations – Year Ended December 31, 2016 as compared to Year Ended December 31, 2015

The Company's selected summary financial and operating data for the years ended December 31, 2016 and 2015 were as follows:

	Year Ended December 31,		Increase (Decrease)	
(dollars in thousands)	2016	2015	Amount	%
Revenue:				
Product	$ 2,320	$ 1,861	$ 459	25
Service	322	-	322	-
License	-	316	(316)	-

Total revenue	2,642	2,177	465	21
Cost of revenue:				
Product	1,974	2,309	(335)	(15)
Service	724	-	724	-
Total cost of revenue	2,698	2,309	389	17
Gross loss	(56)	(132)	76	(58)
Operating expenses:				
Research and development	2,172	3,751	(1,579)	(42)
Sales and marketing	6,798	9,833	(3,035)	(31)
General and administrative	5,928	5,533	395	7
Total operating expenses	14,898	19,117	(4,219)	(22)
Loss from operations	(14,954)	(19,249)	4,295	(22)
Interest (expense) / income, net	(28)	28	(56)	(200)
Other income (expense), net	14	106	(92)	(87)
Net loss	$ (14,968)	$ (19,115)	$ 4,147	(22)

Product Revenue. Product revenue was $2,320,000 for the year ended December 31, 2016 compared to $1,861,000 for the same period in 2015. Revenue for ASPiRA LABS is being recognized when the OVA1 test is being performed or when amounts that will ultimately be realized can be estimated. All other ASPiRA LABS revenue is being recognized on a cash basis and thus recognition of revenue lags the performance of some OVA1 tests. Virtually all OVA1 tests have been performed at ASPiRA LABS since the August 10, 2015 cutover date from Quest Diagnostics. We realized product revenue for all tests performed by Quest Diagnostics in 2015 at the time the OVA1 test was performed at a $125.35 fixed fee per test.

Our total OVA1 volume was 9,125 for 2016. All of the OVA1 tests were performed by ASPiRA LABS. Our total OVA1 volume was 13,598 for 2015. This was comprised of 8,937 tests performed by Quest Diagnostics and 4,661 OVA1 tests performed by ASPiRA LABS. The decrease in volume from 2015 to 2016 was due primarily to the transition of OVA1 testing from Quest Diagnostics to ASPiRA LABS. Product revenue, however, increased 25% in 2016 compared to 2015 despite the decrease in volume due to gains in average unit price in 2016 and as compared to the fixed fee per test from Quest Diagnostics in 2015.

Service Revenue. Service revenue was $322,000 for the year ended December 31, 2016. There was no service revenue in 2015 as ASPiRA IVD began operations in June 2016. We expect service revenue to increase in 2017 as ASPiRA IVD will have a full year of operations in 2017 compared to a partial year in 2016.

License Revenue. There was no license revenue recognized for the year ended December 31, 2016 compared to $316,000 for the same period in 2015. License revenue in 2015 consisted of the remaining deferred Quest Diagnostics license revenue. We do not expect to recognize any license revenue in future periods.

Cost of Revenue - Product. Cost of product revenue for the year ended December 31, 2016 decreased $335,000 or 15% compared to the same period in 2015. Cost of product revenue for the year ended December 31, 2015 included costs associated with processing the full volume of OVA1 tests at ASPiRA LABS after the cutover of volume from Quest Diagnostics to ASPiRA LABS on August 10, 2015, including significant one-time costs during the cutover period. Thus, cost of product revenue in 2016 decreased compared to 2015 even though ASPiRA LABS processed 9,125 OVA1 tests in 2016 compared to 4,661 in 2015.

Cost of Revenue - Service. Cost of service revenue was $724,000 for the year ended December 31, 2016. There was no cost of service revenue in 2015 as ASPiRA IVD did not commence operations until 2016. We expect the cost of service revenue to increase in 2017 as ASPiRA IVD will have a full year of operational costs in 2017 compared to a partial year in 2016.

Research and Development Expenses. Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with our collaborators and strategic partners. Research and development expenses decreased by $1,579,000, or 42%, for the year ended December 31, 2016 compared to the same period in 2015. This decrease was mainly due to decreases in collaborations, clinical trials, and consulting as Overa was cleared in March 2016 and the March 31, 2016 expiration of our collaboration agreement with JHU and lower personnel and personnel related expenses due to our February 2016 restructuring and other terminations. Ongoing product pipeline development was performed internally in 2016 at a lower cost including our pelvic mass specimen and data repository for which collection of patient consents under IRB and cataloguing of serum samples for future research purposes. We expect research and development expenses to decrease in 2017 compared to 2016 due to the changes described above and as we focus current investment from raw research and development to informatics infrastructure supporting our "cloud"/web services platform.

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 and Overa. 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 decreased by $3,035,000, or 31%, for the year ended December 31, 2016 compared to the same period in 2015. This decrease was primarily due to a reduction in personnel and personnel expenses due to our February 2016 restructuring and decreases in consulting services. We expect sales and marketing expenses to decrease in future periods due to lower headcount expected in 2017 compared to full year 2016.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses, and other infrastructure expenses. General and administrative expenses increased by $395,000, or 7%, for the year ended December 31, 2016 compared to the same period in 2015. We expect general and administrative expenses to decrease in 2017 compared to 2016 as start-up costs for ASPiRA IVD incurred in 2016 prior to the June 2016 opening of ASPiRA IVD not being repeated in 2017.

Interest Income (Expense), Net. Interest expense was $28,000 in 2016, compared to interest income of $28,000 in 2015. 2015 interest income was earned on our cash investment balances while 2016 interest expense was due to an equipment lease and the DECD loan.

Other Income (Expense), Net. Net other income decreased by $92,000, or 87%, for the year ended December 31, 2016 compared to the same period in 2015. Other income for 2015 related to recognition of one-time items related to the March 11, 2015 agreement with Quest Diagnostics.

Liquidity and Capital Resources

We plan to continue to expend resources in the selling and marketing of OVA1 and Overa and developing additional diagnostic tests.

In July 2015, we completed the sale of 9,602,500 shares of Vermillion common stock, at a price to the public of $1.96 per share, including 1,252,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in an underwritten public offering at a price of $1.96 per share. Net proceeds from the offering were approximately $17,495,000 after deducting underwriting discounts and offering expenses.

On March 22, 2016, we entered into the Loan Agreement pursuant to which we may borrow up to $4,000,000 from the DECD. Proceeds from the loan were utilized primarily to fund the build-out, information technology infrastructure and other costs related to our Trumbull, Connecticut facility and operations. The loan bears interest at a fixed rate of 2.0% per annum and requires equal monthly payments of principal and interest until maturity, which occurs on April 15, 2026. As security for the loan, we have granted the DECD a blanket security interest in our personal and intellectual property. The DECD's security interest in our intellectual property may be subordinated to a qualified institutional lender. Under the terms of the agreement, we may be eligible for forgiveness of up to $2,000,000 of the principal amount of the loan if we achieve certain job creation and retention milestones measured by March 1, 2018. If we are unable to meet these job creation milestones within the allotted timeframe or do not maintain our Connecticut operations for a period of 10 years, the DECD may require early repayment of a portion or all of the loan depending on job attainment as compared to the required amount.

An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The Loan Agreement provides that the remaining $2,000,000 will be disbursed if and when the Company achieves certain future milestones. The loan may be prepaid at any time without premium or penalty.

On February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased 3,747,125 shares of Vermillion common stock at a price of $1.40 per share. Vermillion also issued warrants to purchase shares of common stock at a price of $0.125 per warrant share in the private placement. Net proceeds of the private placement were approximately $5,100,000 after deducting offering expenses. The warrants are exercisable for 2,810,338 shares of Vermillion common stock at $1.80 per share. The warrants may be exercised from time to time beginning August 17, 2017 and expire on the fifth anniversary of the date of issuance or, if earlier, five business days after the Company delivers notice that the closing price per share of its common stock exceeded the exercise price for 20 consecutive trading days during the exercise period. In addition, there are warrants outstanding from the Company's December 2014 private placement for 4,166,659 shares of Vermillion common stock at $2.00 per share which expire on December 23, 2017.

The Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2016, we had an accumulated deficit of $385,556,000 and stockholders' equity of $3,762,000. On December 31, 2016, we had $5,242,000 of cash and cash equivalents and $2,561,000 of current liabilities. The Company expects to incur a net loss in 2017 as well.

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 and services to be our only material, recurring source of cash in 2017.

Our management believes that our current working capital as of December 31, 2016 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 exercise of common stock warrants, public and private equity financing, collaborative arrangements, licensing arrangements, grants and government funding, strategic alliances and debt financing.

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 Overa; and
- the insurance payer community's acceptance of and reimbursement for OVA1 and/or Overa.

Cash and cash equivalents as of December 31, 2016 and December 31, 2015 were $5,242,000 and $18,642,000, respectively. At December 31, 2016 and 2015, working capital was $3,547,000 and $16,015,000, respectively.

Net cash used in operating activities was $13,963,000 for the year ended December 31, 2016, resulting primarily from $14,968,000 net loss incurred partially offset by $1,179,000 of stock-based compensation expense and $723,000 of depreciation and amortization expense. Net cash used in operating activities also included $903,000 of cash used from changes in operating assets and liabilities and primarily from decreases in accrued liabilities.

Net cash used in operating activities was $18,365,000 for the year ended December 31, 2015, resulting primarily from $19,115,000 net loss incurred as adjusted for non-cash license revenues of $316,000, partially offset by $1,227,000 of stock-based compensation expense. Net cash used in operating activities also included $415,000 of cash used from changes in operating assets and liabilities and primarily from decreases in deferred revenue and accounts payable.

Net cash used in investing activities was $1,261,000 for the year ended December 31, 2016, due to purchases of computer equipment and software and build-out of the ASPiRA IVD lab at our Trumbull, Connecticut facility.

Net cash used in investing activities was $1,055,000 for the year ended December 31, 2015, due to purchases of computer equipment and software, machinery and equipment and construction in progress.

Net cash provided by financing activities was $1,824,000 for the year ended December 31, 2016, which consisted primarily of proceeds from the DECD loan less loan repayments made.

Net cash provided by financing activities was $15,097,000 for the year ended December 31, 2015, due to receipt of $17,495,000 in July 2015 from our follow on public offering of common stock, partially offset by the repurchase of common stock from Quest Diagnostics in the amount of $1,291,000, the repayment of short-term debt of $1,069,000 to Quest Diagnostics and $122,000 of offering expenses relating to our December 2014 private placement.

Off-Balance Sheet Arrangements

As of December 31, 2016, 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 balance sheets as of December 31, 2016 and 2015, consolidated statements of operations for the years ended December 31, 2016 and 2015, consolidated statements of changes in stockholders' equity for the years ended December 31, 2016 and 2015, consolidated statements of cash flows for the years ended December 31, 2016 and 2015 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 SEC's rules and regulations, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure.

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act, as of December 31, 2016.

Based on that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of December 31, 2016, our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15(d)-15(e) under the Exchange Act, were effective.

Management Report on Internal Control over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over our financial reporting. We have assessed the effectiveness of internal control over financial reporting as of December 31, 2016. 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, 2016 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, 2016, 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, 2016 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 “Proposal 1: Election of Directors,” "Corporate Governance," "Management" and "Section 16(a) Beneficial Ownership Reporting Compliance," of our proxy statement relating to our 2017 Annual Meeting of Stockholders to be held in 2017 (the “2017 Proxy Statement”) is incorporated by reference.

Our code of ethics is applicable to all employees, including both our Chief Executive Officer and Principal Financial Officer. This code of ethics is publicly available on our website at 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 2017 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 2017 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 "Corporate Governance" of the 2017 Proxy Statement is incorporated by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information appearing under the heading “Ratification of the Selection of the Independent Registered Public Accounting Firm for Vermillion” of the 2017 Proxy Statement is incorporated by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

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

ITEM 16. FORM 10-K SUMMARY

None.

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. as of December 31, 2016 and 2015 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits 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, 2016 and 2015, 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 30, 2017

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

	December 31,	
	2016	**2015**
Assets		
Current assets:		
Cash and cash equivalents	$ 5,242	$ 18,642
Accounts receivable	275	87
Prepaid expenses and other current assets	498	550
Inventories	93	87
Total current assets	6,108	19,366
Property and equipment, net	1,911	1,504
Other assets	-	90
Total assets	$ 8,019	$ 20,960
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 881	$ 988
Accrued liabilities	1,464	2,208
Short-term debt	182	-
Other current liabilities	34	155
Total current liabilities	2,561	3,351
Long-term debt	1,667	-
Other non-current liabilities	29	63
Total liabilities	4,257	3,414
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, 2016 and 2015	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized; 52,328,492 and 52,113,059 shares issued and outstanding at December 31, 2016 and 2015, respectively	52	52
Additional paid-in capital	389,266	388,082
Accumulated deficit	(385,556)	(370,588)
Total stockholders' equity	3,762	17,546
Total liabilities and stockholders' equity	$ 8,019	$ 20,960

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,	
	2016	**2015**
Revenue:		
Product	$ 2,320	$ 1,861
Service	322	-
License	-	316
Total revenue	2,642	2,177
Cost of revenue:[1]		
Product	1,974	2,309
Service	724	-
Total cost of revenue	2,698	2,309
Gross loss	(56)	(132)
Operating expenses:		
Research and development[2]	2,172	3,751
Sales and marketing[3]	6,798	9,833
General and administrative[4]	5,928	5,533
Total operating expenses	14,898	19,117
Loss from operations	(14,954)	(19,249)
Interest (expense) income, net	(28)	28
Other income (expense), net	14	106
Net loss	$ (14,968)	$ (19,115)
Net loss per share - basic and diluted	$ (0.29)	$ (0.41)
Weighted average common shares used to compute basic and diluted net loss per common share	52,197,969	47,124,261
Non-cash stock-based compensation expense included in expenses:		
(1) Cost of revenue	$ 115	$ 40
(2) Research and development	71	137
(3) Sales and marketing	108	209
(4) General and administrative	885	841

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, 2014	43,115,790	$ 43	$ 370,685	$ (351,473)	$ 19,255
Net loss	-	-	-	(19,115)	(19,115)
Common stock issued in conjunction with follow-on public offering, net of issuance costs	9,602,500	10	17,363	-	17,373
Common stock issued in conjunction with exercise of stock options	59,583	-	97	-	97
Common stock issued for restricted stock awards	195,781	-	401	-	401
Stock compensation charge	-	-	826	-	826
Repurchase of common stock	(860,595)	(1)	(1,290)	-	(1,291)
Balance at December 31, 2015	52,113,059	52	388,082	(370,588)	17,546
Net loss	-	-	-	(14,968)	(14,968)
Common stock issued in conjunction with exercise of stock options	3,541	-	5	-	5
Common stock issued for restricted stock awards	211,892	-	334	-	334
Stock compensation charge	-	-	845	-	845
Balance at December 31, 2016	52,328,492	$ 52	$ 389,266	$ (385,556)	$ 3,762

See accompanying Notes to Consolidated Financial Statements

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

	Year Ended December 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (14,968)	$ (19,115)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt	-	(37)
Non-cash license revenue	-	(316)
Loss on sale and disposal of property and equipment	6	-
Depreciation and amortization	723	291
Stock-based compensation expense	1,179	1,227
Changes in operating assets and liabilities:		
Accounts receivable	(188)	80
Prepaid expenses and other assets	142	(106)
Inventories	(6)	(87)
Accounts payable, accrued liabilities and other liabilities	(851)	(129)
Deferred revenue	-	(173)
Net cash used in operating activities	(13,963)	(18,365)
Cash flows from investing activities:		
Purchase of property and equipment	(1,261)	(282)
Construction in progress	-	(773)
Net cash used in investing activities	(1,261)	(1,055)
Cash flows from financing activities:		
Repurchase of common stock	-	(1,291)
Issuance costs related to 2014 private placement	-	(122)
Proceeds from public offering of common stock, net of issuance costs	-	17,495
Repayment of short-term debt	-	(1,069)
Proceeds from issuance of DECD loan, net of issuance costs	1,967	-
Principal repayment of DECD loan	(118)	-
Repayment of capital lease obligations	(30)	(13)
Proceeds from issuance of common stock from exercise of stock options	5	97
Net cash provided by financing activities	1,824	15,097
Net decrease in cash and cash equivalents	(13,400)	(4,323)
Cash and cash equivalents, beginning of year	18,642	22,965
Cash and cash equivalents, end of year	$ 5,242	$ 18,642
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	38	7
Supplemental disclosure of noncash investing and financing activities:		
Equipment acquired through capital lease agreements	-	107
Changes in other current liabilities related to equipment	-	125

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. The Company sells the OVA1™ and Overa™ risk of malignancy tests for ovarian cancer ("OVA1" and "Overa"). Until August 10, 2015, the Company distributed OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics") (see Note 3). Since August 10, 2015, the Company has distributed all tests through Vermillion's wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, Inc. ("ASPiRA LABS"). The Company also offers in-vitro diagnostic ("IVD") trial services to third-party customers through its wholly-owned subsidiary, ASPiRA IVD, Inc. ("ASPiRA IVD"), which was formed in April 2016. ASPiRA IVD is a specialized, CLIA certified, laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. ASPiRA IVD was built around a core of laboratory expertise and a United States Food and Drug Administration ("FDA")-compliant quality system, and strives to deliver accurate and reliable results to its third-party customers suitable for FDA submission.

Liquidity

In July 2015 the Company completed the sale of 9,602,500 shares of Vermillion common stock, at a price to the public of $1.96 per share, including 1,252,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in an underwritten public offering at a price of $1.96 per share. Net proceeds from the offering were approximately $17,495,000 after deducting underwriting discounts and offering expenses.

As discussed in Note 6, on March 22, 2016, the Company entered into a loan agreement (the "Loan Agreement") pursuant to which it may borrow up to $4,000,000 from the State of Connecticut Department of Economic and Community Development ("DECD"). An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The remaining $2,000,000 will be advanced if and when the Company achieves certain future milestones.

On February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased 3,747,125 shares of Vermillion common stock at a price of $1.40 per share. Vermillion also issued warrants to purchase shares of common stock at a price of $0.125 per warrant share in the private placement. Net proceeds of the private placement were approximately $5,100,000 after deducting offering expenses. The warrants are exercisable for 2,810,338 shares of Vermillion common stock at $1.80 per share. The warrants may be exercised from time to time beginning August 17, 2017 and expire on the fifth anniversary of the date of issuance or, if earlier, five business days after Vermillion delivers notice that the closing price per share of its common stock exceeded the exercise price for 20 consecutive trading days during the exercise period.

The Company has incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately $385,556,000 at December 31, 2016. The Company expects to incur a net loss in 2017 as well. 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 exercise of common stock warrants, (*e.g.*, the warrants to purchase 4,166,659 shares of Vermillion common stock at $2.00 per share, which warrants were issued in December 2014 and expire on December 23, 2017), public and private equity offerings, debt financing, collaborations, licensing arrangements, grants and government funding and strategic alliances. 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 and ASPiRA IVD sales to be the Company's only material, recurring source of cash in 2017.

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 revenue recognition as well as 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 ("ASC") 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 funds are insured by the FDIC up to a maximum of $250,000, but are otherwise unprotected. 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

Accounts receivable are derived from sales made to customers 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, 2016 was from 16 customers. Accounts receivable at December 31, 2015 was from 14 customers.

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 has adopted ASC 954-605, *Health Care Entities—Revenue Recognition*, as revenue from laboratory services has become significant to the Company. The Company's product revenue is generated by performing diagnostic services using its OVA1 and Overa tests, and the service is completed upon the delivery of test results to the prescribing physician. The Company recognizes revenue related to billings for Medicare and commercial payers on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be realized can be estimated. Until a contract has been negotiated with a commercial payer or governmental program, the OVA1 and Overa tests may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with the Company that commit them to pay any portion of the cost of the tests in the event that their insurance declines to reimburse the Company. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment from the patient, the related revenue is only recognized upon cash receipt.

Estimates of amounts that the Company will ultimately realize require significant judgment by management. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and the Company may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with the patient's health plan. Some payers may not cover the OVA1 or Overa test as ordered by the prescribing physician under their reimbursement policies. The Company pursues reimbursement from such patients on a case-by-case basis. In the absence of contracted reimbursement coverage or the ability to estimate the amount that will ultimately be realized for the Company's services, revenue is recognized when cash is received.

Service Revenue: The Company's service revenue is generated by performing IVD trial services for third-party customers. In accordance with SAB Topic 13, service revenue is recognized when the following revenue recognition criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

License Revenue: Under the terms of the secured line of credit with Quest Diagnostics, 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 accounted 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 did not have a sufficient history of product sales that provided a reasonable basis for estimating future product sales. License revenue was 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 $316,000 was 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 general and administrative expenses on the Consolidated Statements of Operations. Such costs aggregated approximately $308,000 and $215,000 for the years ended December 31, 2016 and 2015, 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, as amended (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 was estimated using a combination of historical and peer group volatility for a blended volatility in deriving the expected volatility assumption through December 31, 2015. Beginning January 1, 2016, expected stock price volatility is estimated using Company historical volatility only. The Company made an assessment that blended volatility was more representative of future stock price trends than just using historical or peer group volatility, which corresponds to the expected life of the options, through December 31, 2015. Beginning January 1, 2016, the Company made an assessment that Company historic volatility is more representative of future stock price trends than just using blended volatility. The expected dividend yield is based on the estimated annual dividends that are 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 is recalculated each reporting period using a Black-Scholes option valuation model. A change in assumptions used in the calculations, including changes in the fair value of common stock, can result in significant changes in the amounts recorded from one reporting period to another.

Contingencies

The Company accounts for contingencies in accordance with ASC 450 *Contingencies* ("ASC 450") which requires that an estimated loss from a loss contingency be accrued when (i) information available prior to issuance of the financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and (ii) when the amount of the loss can be reasonably estimated. Accounting for contingencies such as legal and contract dispute matters requires the use of management's judgment. Management believes that the Company's 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, *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 June 2016, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This update changes the impairment model from the currently used incurred loss methodology to an expected loss methodology, which will result in the more timely recognition of losses. The ASU is scheduled to be effective in 2020. The Company is currently assessing the impact of this ASU on our financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), Compensation - Stock Compensation. The new guidance simplifies several aspects of the accounting for share-based payments, including immediate recognition of all excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within that reporting period. The adoption of this standard is not expected to have a material effect on our financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of the pending adoption of the new standard on the consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11 *Inventory (Topic 330): Simplifying the Measurement of Inventory* ("ASU No. 2015-11"). ASU 2015-11 changes the measurement of inventory from the lower of cost or market to the lower of cost and net realizable value. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2016. The Company does not anticipate a material impact on its consolidated financial statements from the adoption of this ASU.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU No. 2014-09"). ASU 2014-09 removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. This guidance requires that an entity depict the consideration by applying a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On April 1, 2015, the FASB voted for a one-year deferral of the effective date of the new revenue recognition standard, ASU No. 2014-09. On July 15, 2015, the FASB affirmed these changes, which requires public entities to apply the amendments in ASU 2014-09 for annual reporting beginning after December 15, 2017. Early adoption is permitted beginning after December 31, 2016, the original effective date in ASU 2014-09. The Company is currently evaluating the impact of this ASU on its consolidated financial statements and related disclosures.

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

In July 2005, the Company entered into a Strategic Alliance Agreement (as amended, the "Strategic Alliance Agreement") with Quest Diagnostics to develop and commercialize 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. 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. Through December 31, 2014, the entire loan was either repaid or forgiven except for $1,106,000 which was in dispute. The dispute regarding the balance of the loan was resolved on March 11, 2015 for a payment to Quest Diagnostics totaling $1,069,000. As a result of this settlement, the Company recognized one-time items during the year ended December 31, 2015, including product revenue of $163,000, license revenue of $202,000, gain on extinguishment of debt of $37,000 and reversal of other liabilities totaling $41,000.

In March 2015, the Company reached an agreement with Quest Diagnostics that terminated the Strategic Alliance Agreement and the Company's prior loan agreement with Quest Diagnostics. The Company also entered into a commercial agreement with Quest Diagnostics. Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Vermillion's wholly-owned subsidiary, ASPiRA LABS, as of August 10, 2015. Pursuant to this agreement, as amended as of March 11, 2017, Quest Diagnostics is continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing through at least March 11, 2018 in exchange for a market value fee. Per the terms of the new commercial agreement, the Company will not offer to existing or future Quest Diagnostics customers tests that Quest Diagnostics offers.

On June 17, 2015, the Company entered into a Share Repurchase Agreement (the "Share Repurchase Agreement") with Quest Diagnostics. Pursuant to the Share Repurchase Agreement, the Company purchased from Quest Diagnostics 860,595 shares of Vermillion common stock for a total purchase price of $1,290,892, or $1.50 per share. The price per share was agreed to in principle in March 2015 and based upon a simple average of the closing prices per share of Vermillion common stock for a trailing 60-day period at that time. This price was then reduced by a negotiated discount. Subsequently, the common stock repurchased from Quest Diagnostics was retired.

Accounts receivable from Quest Diagnostics totaled $0 and $1,000 at December 31, 2016 and 2015, respectively.

NOTE 4: PROPERTY AND EQUIPMENT

The components of property and equipment as of December 31, 2016 and 2015 were as follows:

	December 31,	
(in thousands)	2016	2015
Machinery and equipment	$ 1,381	$ 841
Demonstration equipment	39	39
Computer equipment and software	1,029	428
Furniture and fixtures	127	41
Leasehold improvements	704	36
Construction in progress	-	773
Gross property and equipment	3,280	2,158
Accumulated depreciation and amortization	(1,369)	(654)
Property and equipment, net	$ 1,911	$ 1,504

Depreciation expense for property and equipment was $723,000 and $291,000 for the years ended December 31, 2016 and 2015, respectively. The accumulated amortization of assets under capital lease obligations was $116,000 and the net book value of assets under capital lease obligations was $116,000 as of December 31, 2016. The accumulated amortization of assets under capital lease obligations was $39,000 and the net book value of assets under capital lease obligations was $193,000 as of December 31, 2015.

Construction in progress represented $289,000 in leasehold improvements and $484,000 in information technology build-out at our Trumbull, Connecticut facility in 2015. The facility was occupied and in operation beginning in January 2016.

NOTE 5: ACCRUED LIABILITIES

The components of accrued liabilities as of December 31, 2016 and 2015 were as follows:

	December 31,	
(in thousands)	2016	2015
Payroll and benefits related expenses	$ 541	$ 798
Collaboration and research agreements expenses	414	339
Professional services	217	717
Tax-related liabilities	4	40
Other accrued liabilities	288	314
Total accrued liabilities	$ 1,464	$ 2,208

NOTE 6: COMMITMENTS, CONTINGENCIES AND DEBT

As of December 31, 2016, the annual amounts of future minimum payments under certain of the Company's contractual obligations were:

	Payments Due by Period				
(in thousands)	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating Leases	$ 592	$ 169	$ 247	$ 176	$ -
Capital Leases	61	41	20	-	-
Total accrued liabilities	$ 653	$ 210	$ 267	$ 176	$ -

In addition, the Company has minimum royalty obligations (described below in non-cancelable collaboration obligations and other commitments) and minimum quantities of reagent purchases from the manufacturer of certain laboratory instruments.

Development Loan

On March 22, 2016, the Company entered into the Loan Agreement with the DECD, pursuant to which the Company may borrow up to $4,000,000 from the DECD. Proceeds from the loan were utilized primarily to fund the build-out, information technology infrastructure and other costs related to the Company's Trumbull, Connecticut facility and operations. The loan bears interest at a fixed rate of 2.0% per annum and requires equal monthly payments of principal and interest until maturity, which occurs on April 15, 2026. As security for the loan, the Company has granted the DECD a blanket security interest in the Company's personal and intellectual property. The DECD's security interest in the Company's intellectual property may be subordinated to a qualified institutional lender. Under the terms of the Loan Agreement, the Company may be eligible for forgiveness of up to $2,000,000 of the principal amount of the loan if the Company achieves certain job creation and retention milestones by March 1, 2018. Conversely, if the Company is unable to meet these job creation milestones, namely, hiring 40 full time employees with a specified average annual salary within the allotted timeframe and retaining those employees for a two year period or does not maintain the Company's Connecticut operations for a period of 10 years, the DECD may require early repayment of a portion or all of the loan depending on job attainment as compared to the required amount plus a penalty of 5%.

An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The Agreement provides that the remaining $2,000,000 will be advanced if and when the Company achieves certain future milestones including meeting a specified Company revenue target and meeting the job creation milestone described above. The loan may be prepaid at any time without premium or penalty.

The balance of the DECD loan was $1,849,000 at December 31, 2016.

Operating Leases

The Company leases facilities to support its business of discovering, developing and commercializing diagnostic tests in the fields of gynecologic disease, including its principal facility and CLIA laboratory located in Austin, Texas. As of December 31, 2016 there was an Austin, Texas lease which included an annual base rent of $67,000 and annual estimated common area charges, taxes and insurance of 39,000. The lease expires on May 31, 2017.

In October 2015, the Company entered a lease agreement for a facility in Trumbull, Connecticut. The lease includes initial payments for the buildout of leasehold improvements to the office space, which are estimated to be approximately $438,000. The term of the lease is five years beginning after the initial date of occupancy in January 2016 and a rent abatement period of five months. The lease includes an aggregate annual base rent of $32,000 and annual estimated common area charges, taxes and insurance of $91,000. Rental expense under operating leases for the years ended December 31, 2016 and 2015 totaled $234,000 and $190,000, respectively.

Capital Lease

In April 2015, the Company leased a laboratory instrument for a total initial payment of $125,000 and ongoing payments of approximately $3,500 per month for 36 months after delivery. The agreement also requires minimum annual purchases of reagents from the manufacturer of the equipment. The laboratory instrument was placed into service on July 1, 2015.

The accumulated amortization of assets under capital lease obligations was $116,000 and the net book value of assets under capital lease obligations was $116,000 as of December 31, 2016. The accumulated amortization of assets under capital lease obligations was $39,000 and the net book value of assets under capital lease obligations was $193,000 as of December 31, 2015.

Non-cancelable Collaboration Obligations and Other Commitments

The Company had a research collaboration agreement with The Johns Hopkins University School of Medicine ("JHU") directed at the discovery and validation of biomarkers in human subjects, including but not limited to clinical application of biomarkers in the understanding, diagnosis and management of human disease. This agreement expired on March 31, 2016. Collaboration expenses under the JHU collaboration were $264,000 and $600,000 for the years ended December 31, 2016 and 2015, 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. Royalty expense for the years ended December 31, 2016 and 2015 totaled $92,000 and $74,000, respectively.

Contingent Liabilities

From time to time, the Company is involved in legal proceedings and regulatory proceedings arising from operations. The Company establishes reserves for specific liabilities in connection with legal actions that management deems to be probable and estimable. 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

2017 Private Placement

On February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased 3,747,125 shares of Vermillion common stock at a price of $1.40 per share. Vermillion also issued warrants to purchase shares of common stock at a price of $0.125 per warrant share in the private placement. Net proceeds of the private placement were approximately $5,100,000 after deducting offering expenses. The warrants are exercisable for 2,810,338 shares of Vermillion common stock at $1.80 per share. The warrants may be exercised from time to time beginning August 17, 2017 and expire on the fifth anniversary of the date of issuance or, if earlier, five business days after Vermillion delivers notice that the closing price per share of its common stock exceeded the exercise price for 20 consecutive trading days during the exercise period.

The sale of common stock and issuance of 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 $804,000 and to the common stock is approximately $4,296,000.

2015 Registered Offering

On July 17, 2015 the Company completed the sale of 9,602,500 shares of Vermillion common stock, including 1,252,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in an underwritten public offering at a price of $1.96 per share. The Company received net proceeds from the offering of $17,495,000 after deducting underwriting discounts and offering expenses.

Warrants

Warrants outstanding as of December 31, 2016 and 2015 were as follows:

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

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, 2016 and 2015 was as follows:

(In thousands, except per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
Year ended December 31, 2015:			
Net loss - basic	$ (19,115)	47,124,261	$ (0.41)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards	-	-	
Net loss - diluted	$ (19,115)	47,124,261	$ (0.41)
Year ended December 31, 2016:			
Net loss - basic	$ (14,968)	52,197,969	$ (0.29)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards	-	-	
Net loss - diluted	$ (14,968)	52,197,969	$ (0.29)

Due to net losses for the years ended December 31, 2016 and 2015, 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, 2016 and 2015 were as follows:

	Year Ended December 31, 2016	2015
Stock options	3,451,073	3,317,811
Stock warrants	4,166,659	4,587,018
Unvested restricted stock awards	7,752	-
Potential common shares	7,625,484	7,904,829

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. There were no stock options under the 2000 Stock Plan exercised during the year ended December 31, 2016 or 2015. 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 Vermillion's 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. On June 18, 2015, Vermillion's stockholders approved an increase of 4,500,000 in the number of shares available for issuance under the 2010 Plan for a total of 8,122,983 shares. Unexercised options generally expire ten years from the date of grant. Options to purchase 3,541 and 59,583 shares of common stock were exercised during the year ended December 31, 2016 and 2015, respectively.

During the year ended December 31, 2016, Vermillion issued to Vermillion's Board of Directors 197,727 shares of restricted stock from the 2010 Plan having a fair value of $310,000 as payment for services rendered in 2016. The Company also issued to certain consultants 14,165 shares of restricted stock from the 2010 Plan having a fair value of $18,000.During the year ended December 31, 2015, Vermillion issued to Vermillion's Board of Directors 195,781 shares of restricted stock from the 2010 Plan having a fair value of $401,000 as payment for services rendered in 2015.

Subsequent to December 31, 2016, the Company awarded 131,250 shares of restricted stock from the 2010 Plan having a fair value of approximately $281,000 to Vermillion's Board of Directors as payment for services in 2017. The restricted stock vests 50% on June 1, 2017 and 25% each on September 1, 2017 and December 1, 2017. The Company also granted approximately 986,000 stock options with an exercise price of $2.14 per share to certain of the Company's officers, employees and consultants. These stock options generally vest 25% on each of the four anniversaries of the grant date. In addition, the Company granted certain officers options to purchase 250,000 shares of Vermillion common stock with an exercise price of $2.14 per share with performance-based vesting based on certain metrics through December 31, 2017. These options vest 25% on each of the four anniversaries of the grant date if the performance-based metrics are met.

The activity related to shares available for grant under the 2000 Plan and the 2010 Plan for the years ended December 31, 2016 and 2015 was as follows:

	2000 Stock Plan	2010 Stock Option Plan	Total
Shares available at December 31, 2014	-	737,434	737,434
Shares added		4,500,000	4,500,000
Options canceled	3,800	69,352	73,152
Reduction in shares reserved	(3,800)	-	(3,800)
Options granted	-	(1,739,500)	(1,739,500)
Restricted stock units granted	-	(195,781)	(195,781)
Shares available at December 31, 2015	-	3,371,505	3,371,505
Options canceled	33,050	2,243,217	2,276,267
Reduction in shares reserved	(33,050)	-	(33,050)
Options granted	-	(2,413,070)	(2,413,070)
Restricted stock units granted	-	(211,892)	(211,892)
Shares available at December 31, 2016	-	2,989,760	2,989,760

The stock option activity under the 2000 Plan and 2010 Plan for the years ended December 31, 2016 and 2015 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Options outstanding at December 31, 2014	1,711,046	$ 2.62	$ 178	7.82
Granted	1,739,500	1.99		
Exercised	(59,583)	1.62		
Canceled	(73,152)	3.29		
Options outstanding at December 31, 2015	3,317,811	$ 2.29	$ 91	8.24
Granted	2,413,070	1.33		
Exercised	(3,541)	1.30		
Canceled	(2,276,267)	2.21		
Options outstanding at December 31, 2016	3,451,073	$ 1.70	$ 41	8.46
Shares exercisable:				
December 31, 2016	1,084,140	$ 2.29	$ -	6.96
Shares expected to vest:				
December 31, 2016	1,940,885	$ 1.43	$ 41	9.15

The range of exercise prices for options outstanding and exercisable at December 31, 2016 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	835,000	$ 0.94	9.78	4,010	$ 1.30
1.31 - 1.64	1,258,668	1.52	8.82	223,958	1.57
1.65 - 2.08	932,414	1.95	7.58	501,199	1.97
2.09 - 11.55	424,991	3.17	6.76	354,973	3.21
$ 0.01 - $ 11.55	3,451,073	$ 1.70	8.46	1,084,140	$ 2.29

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2016	$ 1	$ 1,562
Year ended December 31, 2015	$ 13	$ 1,864

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, 2016 and 2015 were as follows:

	Year Ended December 31,	
	2016	**2015**
Dividend yield	- %	- %
Volatility	77 %	78 %
Risk-free interest rate	0.96 %	1.76 %
Expected lives (years)	4.0	6.0
Weighted average fair value	$ 0.77	$ 1.37

The allocation of employee stock-based compensation expense by functional area for the years ended December 31, 2016 and 2015 was as follows:

	Year Ended December 31,	
(in thousands)	**2016**	**2015**
Cost of sales	$ 93	$ 40
Research and development	71	137
Sales and marketing	101	209
General and administrative	759	825
Total	$ 1,024	$ 1,211

As of December 31, 2016, total unrecognized compensation cost related to unvested stock option awards was approximately $1,808,000 and the related weighted average period over which it is expected to be recognized was 2.44 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, 2016 and 2015, the Company did not contribute to the 401(k) Plan.

NOTE 10: INCOME TAXES

There was no income tax expense or benefit for the years ended December 31, 2016 or 2015 because of net losses during those years. These net losses were generated from domestic operations.

Based on the available objective evidence and uncertainty about the timing and amount of any future profits, the Company has provided a full valuation allowance against our net deferred tax assets at December 31, 2016 and 2015.

The components of net deferred tax assets at December 31, 2016 and 2015 were as follows:

	Year Ended December 31,	
(in thousands)	2016	2015
Deferred tax assets:		
Net operating losses	$ 22,861	$ 65,341
Amortization - R&D intangibles	5,327	5,919
Other	2,903	3,007
Total deferred tax assets	31,091	74,267
Valuation allowance	(31,091)	(74,267)
Deferred tax assets	$ -	$ -
Deferred tax liabilities:		
Other	$ -	$ -
Deferred tax liabilities	$ -	$ -
Net deferred tax asset	$ -	$ -

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2016 and 2015 was as follows:

	Year Ended December 31,	
	2016	2015
Tax at federal statutory rate	34 %	34 %
State tax, net of federal benefit	1	2
Valuation allowance	291	(36)
Change in warrant valuation	-	-
Net operating loss and credit reduction due to section 382 limitations	(327)	-
Permanent items	(2)	(1)
Other	3	1
Effective income tax rate	- %	- %

As of December 31, 2016, the Company had pre-tax net operating loss carryforwards of approximately 59,000,000 for federal and $167,000,000 for state tax purposes. If not utilized, these carryforwards begin to expire in 2026 for federal purposes and 2017 for state purposes. In 2017, approximately $12,000,000 of the Company's state net operating loss will expire. As of December 31, 2015, we had a net operating loss of approximately $185,000,000 for federal and $160,000,000 for state tax purposes.

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

We believe that Section 382 ownership changes occurred as a result of our follow-on public offerings in 2011, 2013 and 2015. Any limitation may result in the expiration of a portion of the net operating loss and credit carryforwards before utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of our valuation allowance. Due to the existence of a valuation allowance, it is not expected that such limitations, if any, will have an impact on our results of operations or financial position.

We believe that it is more likely than not that the benefit from certain deferred tax assets will not be realized due to the history of our operating losses. In recognition of this risk, we have provided a valuation allowance on the deferred tax assets relating to these assets. The valuation allowance was $31,000,000 and $74,000,000 at December 31, 2016 and 2015, respectively. The decrease of $43,000,000 between 2016 and 2015 is primarily due to adjustments to the deferred tax assets related to the net operating losses.

The Company files income tax returns in the U.S. and in various state jurisdictions with varying statutes of limitations. The Company has not been audited by the Internal Revenue Service or any state income or franchise tax agency. As of December 31, 2016, the Company's federal returns for the years ended 2013 through the current period and most state returns for the years ended 2012 through the current period are still open to examination. In addition, all of the net operating loss carryforwards and research and development credits generated in years earlier than 2013 and 2012, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2015 reflect research and development carryforwards of $5,335,000 and $5,246,000, respectively. The Company has recognized additional deferred tax assets for federal and California research and development credits of $95,000 and $71,000 for the year ended December 31, 2016, respectively.

As of December 31, 2016, our gross unrecognized tax benefits are approximately $10,747,000 which are attributable to research and development credit carryforwards. 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, 2014	$ 5,188	$ 5,135	$ 10,323
Increase in tax position during 2015	147	111	258
Decrease due to expirations	-	-	-
Balance at December 31, 2015	$ 5,335	$ 5,246	$ 10,581
Increase in tax position during 2016	95	71	166
Decrease due to expirations	-	-	-
Balance at December 31, 2016	$ 5,430	$ 5,317	$ 10,747

The increase for the year ended December 31, 2016 relates to a position taken in the current year. The increase for the year ended December 31, 2015 is related to tax positions taken during 2015 and prior years. If the $11 million of unrecognized income tax benefit is recognized, approximately $11 million would impact the effective tax rate in the period in which each of the benefits is recognized.

We do not expect our unrecognized tax benefits to change significantly over the next 12 months. 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 and comprehensive loss. We have not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2016 and 2015. Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

NOTE 11: RELATED PARTY TRANSACTIONS

On January 18, 2016, 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 business strategies and operational plans and was paid $375 per hour or a minimum of $51,750 for the period up to the expiration of the agreement on March 31, 2016. During the year ended December 31, 2016, Mr. Schreiber was paid $52,000 for services provided pursuant to the consulting agreement.

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 30, 2017

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

Date: March 30, 2017

/s/ Eric J. Schoen
Eric J. Schoen
Senior 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) and Director	March 30, 2017
/s/ Eric J. Schoen Eric J. Schoen	Senior Vice President, Finance and Chief Accounting Officer (Principal Financial Officer)	March 30, 2017
/s/ James T. LaFrance James T. LaFrance	Chairman of the Board of Directors	March 30, 2017
/s/ James S. Burns James S. Burns	Director	March 30, 2017
/s/ Veronica G. H. Jordan Veronica G. H. Jordan	Director	March 30, 2017
/s/ David Schreiber David Schreiber	Director	March 30, 2017
/s/ Carl Severinghaus Carl Severinghaus	Director	March 30, 2017
/s/ Eric Varma Eric Varma	Director	March 30, 2017

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	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	
3.2	Certificate of Amendment of Fourth Amended Certificate of Incorporation, effective June 19, 2014	10-Q	001-34810	3.2	August 14, 2014	
3.3	Fifth Amended and Restated Bylaws of Vermillion, Inc., as amended effective June 19, 2014	10-Q	001-34810	3.3	August 14, 2014	
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,	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	Form of Warrant, issued on May 13, 2013	S-3	333-198734	4.4	September 15, 2014	
4.7	Promissory Note by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective March 14, 2016	10-Q	001-34810	10.2	May 16, 2016	
4.8	Securities Purchase Agreement, dated February 13, 2017, among Vermillion, Inc. and the investors listed on Schedule I thereto	8-K	001-34810	99.1	February 17, 2017	
4.9	Form of Warrant, issued February 13, 2017	8-K	001-34810	99.1	February 17, 2017	
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	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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	Vermillion, Inc. Amended and Restated 2010 Stock Incentive Plan #	8-K	001-34810	10.1	December 17, 2013	
10.9	Employment Agreement between Eric J. Schoen and Vermillion, Inc. dated April 4, 2012 #	8-K	001-34810	10.1	April 10, 2012	
10.11	Consulting Agreement between David Schreiber and Vermillion, Inc. dated October 10, 2014	10-K	001-34810	10.24	March 31, 2015	
10.12	Consulting Agreement between David Schreiber and Vermillion, Inc. dated November 5, 2014	10-K	001-34810	10.25	March 31, 2015	
10.13	Consulting Agreement between David Schreiber and Vermillion, Inc. dated January 18, 2016	10-K	001-34810	10.13	March 30, 2016	
10.14	Employment Agreement between Vermillion, Inc. and Fred Ferrara dated April 1, 2015 #	8-K	001-34810	10.1	April 6, 2015	
10.16	Employment Agreement between Vermillion, Inc. and Valerie B. Palmieri effective January 1, 2015 #	8-K	001-34810	99.1	December 17, 2015	
10.17	Global Settlement Agreement and Mutual Release between Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated dated March 11, 2015	10-Q	001-34810	10.4	May 12, 2015	
10.18	Testing and Services Agreement between Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated, dated as of March 11, 2015	10-Q	001-34810	10.5	May 12, 2015	

10.19	Amendment No. 1 to the Testing Services Agreement dated March 11, 2015 among Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated dated April 10, 2015	10-Q	001-34810	10.6	May 12, 2015	
10.20	Amendment No. 2 to Testing and Services Agreement, executed as of March 7, 2017 and effective as of March 11, 2017, by and among Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated	8-K	001-34810	10.1	March 13, 2017	
10.21	Non-Exclusive License Agreement among Quest Diagnostics Clinical Laboratories, Inc., Quest Diagnostics Incorporated, Vermillion, Inc. and ASPiRA LABS, Inc. dated March 11, 2015	10-Q	001-34810	10.7	May 12, 2015	
10.22	Share Repurchase Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated as of June 17, 2015	8-K	001-34810	99.1	June 18, 2015	
10.23	Assistance Agreement by and between the State of Connecticut, acting by and through the Department of Economic and Community Development and Vermillion, Inc. effective March 22, 2016	10-Q	001-34810	10.1	May 16, 2016	
10.24	Patent Security Agreement by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective March 22, 2016	10-Q	001-34810	10.3	May 16, 2016	
10.25	Security Agreement by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective March 22, 2016	10-Q	001-34810	10.4	May 16, 2016	
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					√√
101	Interactive Data Files					√

√ Filed herewith
√√ 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.