ASPIRA WOMEN'S HEALTH INC.

FORM 10-K
(Annual Report)

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Industry	Biotechnology & Medical Research
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2018 or

☐ **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 every Interactive Data File required to be submitted 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 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," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company , indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting common stock held by non-affiliates of the registrant is $ 33,929,264 and is based upon the last sales price as quoted on The NASDAQ Capital Market as of June 30, 2018 .
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 ☐

As of March 22 , 201 9 , the registrant had 75,5 32,748 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 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, 2018 .

VERMILLION, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2018

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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 forward-looking statements regarding our business include the following:

- projections or expectations regarding our future test volumes, revenue , cost of revenue, operating expenses, cash flow, results of operations and financial condition;
- o ur plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders;
- 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 OVA1 , OVA1+ and Overa outside the United States;
- plans to develop new algorithms and molecular diagnostic tests;
- p lans to develop a product or tool combining an OVA1 with results of a symptom index;
- plans to establish our own payer coverage for Overa and expand coverage for OVA1;
- 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 with respect to ASPiRA IVD, Inc. (“ASPiRA IVD”);
- our planned focus on the execution of four 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;
- e xpectation to increase research and development expenses;
- 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”) ;
- p lans to expand our product offerings to additional pelvic disease conditions ;
- plans regarding the commercialization of Overa;
- p lans to develop informatics products and develop and perform laboratory developed tests (“LDTs”);
- plans with respect to the Company’s pelvic mass registry, including anticipated sources of funding;
- o ur ability to improve sensitivity and specificity over traditional diagnostic biomarkers;
- expectations regarding existing and future collaborations and partnerships , including OVA1 , OVA1+ and Overa distribution agreements ;
- 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 OVA1 , OVA1+ and 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, as amended, with the State of Connecticut Department of Economic and Community Development (the "DECD");
- expected expenditures, including the expected increase in expenses related to sales and marketing of OVA1 , OVA1+ and Overa in 2019 ;
- our ability to use our net operating loss carryforwards;
- a nticipated future tax liability under U.S. federal and state income tax legislation;
- expected market adoption of our diagnostic tests, including OVA1 , OVA1+ and Overa;
- expectations regarding our ability to launch new products we develop, license, co-market or acquire;
- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations; and
- expectations regarding 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 discussed 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 continue as a going concern; ability to increase the volume of OVA1 or Overa sales ; 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 comply with Nasdaq's continued listing requirements to remain publicly traded; in the event that we succeed in commercializing OVA1 and Overa outside the United States, the political, economic and other conditions affecting other countries; our ability to continue developing existing technologies; 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; our ability to use intellectual property directed to diagnose biomarkers; our ability to successfully defend our proprietary technology against third parties; future litigation against us, including infringement of intellectual property and product liability exposure; our ability to retain key employees; business interruptions; changes in healthcare policy; our ability to comply with environmental laws; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; our ability to comply with FDA regulations that relate to our products and to obtain any FDA clearance or approval required to develop and perform LDTs; ASPiRA IVD's ability to enter into profitable contracts; ASPiRA IVD's ability to maintain effective information systems without significant interruption; and our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances.

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 .

O ur corporate strategy is to serve as 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. We are currently in the market expansion and growth phase of our strategy having added to our direct sales force in late 2018 and into the first quarter of 2019 .

We expanded our commercial strategy in 2018 through the establishment of medical and advisory support and a Key Opinion Leader Network aligned with our territories in the US . We ultimately plan to globally commercialize OVA1 and 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 . During 2018 we put OVA1, as we have with Overa , on a global testing platform, which allows both tests to be deployed internationally as well as run locally in the United States at major customer sites . 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 Diagnostic Algorithms #1 ("DxA1") and Diagnostic Algorithms #2 ("DxA2"). We anticipate that DxA1 and DxA2 will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value. During the third and fourth quarters of 2018 , we reorganized internally and reinvested in a stronger sales and marketing team in order to better position our new commercial offerings.

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 the combination of multi-modal diagnostics and data. Our goal 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. OVA1 and Overa use the Roche cobas 4000, 6000 and 8000 platform s .

In June 2014, we launched ASPiRA LABS, a Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified national laboratory 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.

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

1) Maximizing the existing OVA1 opportunity in the United States by leading in payer coverage and commercialization of OVA1. This strategy included the launch of a CLIA certified clinical laboratory, ASPiRA LABS, in June 2014, multiple publications, inclusion in the ACOG adnexal mass guidelines, payer traction and finally the addition of OVA1 to CMS National Fee schedule as of January 2018;

2) Expanding the distribution platform beyond the U.S. 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 in March 2016);

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

4) 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 .

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 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 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 2015. Pursuant to this agreement, as amended as of March 1, 2018, Quest Diagnostics has continued to provide blood draw and logistics support by transporting specimens to ASPiRA LABS for testing in exchange for a market value fee . Per the terms of the commercial agreement, we may not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers. As of the date of this Annual Report on Form 10-K, we are in the process of renewing this agreemen t. .

We have active international distribution agreements for Overa with Pro-Genetics LTD in Israel and MacroHealth, Inc. in the Philippines. The MacroHealth , Inc. agreement was our first decentralized international agreement with Overa specimen testing to be performed in the Philippines.

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, a Medicare contractor, covers and reimburses for OVA1 tests performed in certain states, including Texas. Because OVA1 tests are exclusively performed at ASPiRA LABS in Texas, this local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans .

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. Although there are Practice Bulletins, g uidelines do not exist for adnexal masses. ACOG guidelines do exist, however, for ovarian cancer management.

Practice Bulletin N umber 83 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 (“Multivariate Index Assay”) as listed in the bulletin. Based on this, OVA1 has now achieved parity with CA125 as a Level B clinical recommendation for the

management of adnexal masses. 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. "

Studies and Publications

#	Title	First Author and Journal	Year	Study Size	Findings
1	Effect of Surgeon Specialty on Processes of Care and Outcomes for Ovarian Cancer Patients	Earle et al. JCNI 2006	2006	N=3067	Retrospective analysis of Medicare claims showed that only 33% of patients have access to a gynecological oncologist, but gynecological oncologists overall provided superior care.
2	Effectiveness of a multivariate index assay in the preoperative assessment of ovarian tumors	Ueland, et. al. Obstet Gynecol	2011	N=524	Initial OVA1 Clinical Validation. OVA1 detected 76% of malignancies missed by CA125 in a prospective, multi-institutional trial involving 27 primary care and specialty sites throughout the US. Additionally, MIA plus physician assessment identified 86% of malignancies missed by CA125.
3	The Role of the Obstetrician-Gynecologist in Early Detection of Epithelial Ovarian Cancer	ACOG	2011	N/A	Practice Guidance. Discusses practices in evaluating symptomatic patients with physical exam, imaging and tumor markers.
4	An in vitro diagnostic multivariate index assay ("IVDMIA") for ovarian cancer: harvesting the power of multiple biomarkers	Zhen Zhang	2012	N/A	Discusses rationale and strategy for development of IVDMIA, including specifics on OVA1.
5	Adherence to treatment guidelines for ovarian cancer as a measure of quality of care	Bristow, et. al. Obstet Gynecol	2013	N= 13,321	Patients were identified as having epithelial ovarian cancer in the California Cancer Registry. 37.2% of patients received National Comprehensive Cancer Network ("NCCN") guideline adherent care for the treatment of epithelial ovarian cancer. Adherence to NCCN guideline care for the treatment of epithelial ovarian cancer is correlated with improved survival.
6	Impact of a multivariate index assay on referral patterns for surgical management of an adnexal mass	Bristow, et. al. AJOG	2013	N=770	MIA demonstrated statistically significant higher sensitivity (90.2%) for detecting malignancy compared with clinical assessment (73.2%), CA125 (68.3%), and mACOG guidelines (79.3%). However, use of OVA1 does not lead to over-referral.
7	Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay	Bristow, et. al. Gynecologic Oncology	2013	N=494	Second Pivotal Clinical Validation. Primary ovarian cancer was identified in 65 patients (13.2%) with 43.1% having FIGO Stage 1 disease. Overall sensitivity of MIA was 95.7% , and the MIA correctly predicted ovarian malignancy in 91.4% of cases of early stage disease compared to only 65.7% for CA125-II.
8	Disparities in ovarian cancer care quality and survival according to race and socioeconomic status	Bristow, et. al. JNCI	2013	N=47160	Statistically and clinically significant disparities in the quality of ovarian care and overall survival, independent of NCCN guidelines, is observed along both racial and socioeconomic differences.
9	Widespread flaws found in ovarian cancer treatment	Denise Grady, NY times	2013	N/A	Discusses current state of ovarian cancer care and highlighted the problem of lack of referral to proper physician .
10	The effect of ovarian imaging on the clinical interpretation of a multivariate index assay	Goodrich, et. al. AJOG	2014	N=1024	Using OVA1 in conjunction with Ultrasound findings reduces missing ovarian cancer to just 2% (ultrasound alone missed 23% of malignancies and CT scan missed 20%) .

11	Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer	Longoria et al. AJOG 2014	2014	N=1022	OVA1 combined with clinical assessment shows higher sensitivity for early stage ovarian cancer when compared to other biomarkers (CA125 at two cutoffs) and modified ACOG guidelines for adnexal mass triage.
12	Risk Stratification of the Persistent Ovarian Mass with OVA 1	MEDCO Forum, 2014	2014	N/A	Review of current risk stratification and surgical planning using CA125 and OVA1.
13	Performance of the American College of Obstetricians and Gynecologists' Ovarian Tumor Referral Guidelines With a Multivariate Index Assay	Ware Miller et al. 2014	2014	N=590	Study to estimate performance of substitution of OVA1 for CA125 in ACOG guidelines. Substitution resulted in identification of 79% of missed malignancies in premenopausal and 67% of missed malignancies in postmenopausal women.
15	Validation of a second-generation multivariate index assay for malignancy risk of adnexal masses	Coleman, et. al. AJOG 2016	2016	N=493	When compared to MIA, MIA2G had improved specificity (69% vs. 54%) and PPV (40% vs. 31%) with no significant change in sensitivity and NPV.
16	Cost-effectiveness analysis of a multivariate index assay compared to modified American College of Obstetrics and Gynecologists criteria and CA125 in the triage of women with adnexal masses	Forde, et. al. CMRO, 2016	2016	N/A	MIA was cost effective, resulting in fewer reoperations and pretreatment CT Scans; overall resulting in an incremental cost-effectiveness ratio of $35,094 per quality-adjusted life-year gained.
17	The clinical utility of an elevated-risk multivariate index assay score in ovarian cancer patients	Eskander, et. al. CMRO	2016	N=122	Clinical Utility of OVA1 elevated risk result. When OVA1 is used preoperatively for both pre and postmenopausal women with adnexal masses, 94% of the women with elevated MIA scores had their primary surgery with a gynecological oncologist. Of these women, 65 (53%) were found to have ovarian cancer. Previous studies have proven a survival benefit from an ovarian cancer patient being operated on by a gynecological oncologist initially.
18	Evaluation of a Validated Biomarker Test in Combination With a Symptom Index to Predict Ovarian Malignancy	Urban, et al. Int J Gynecol Cancer	2017	N=218	The combination of a symptom index and a multivariate panel had improved accuracy in predicting ovarian cancer for patients undergoing surgery for a pelvic mass.
19	Economic Impact of Increased Utilization of Multivariate Assay Testing to Guide the Treatment of Ovarian Cancer: Implications for Payers	Brodsky, et al. Am Health and Drug Benefits	2017	N=92,843	The results of the budget impact model support the use of OVA1 instead of CA125 by indicating that modest cost savings can be achieved, while reaping the clinical benefits of improved diagnostic accuracy, early disease detection, and reductions in multiple, and possibly unnecessary, referrals to gynecologic oncologists.
21	Combined symptom index and second-generation multivariate biomarker test for prediction of ovarian cancer in patients with a pelvic mass	Urban, et al. Gynecologic Oncology	2018	N=218	The combination of a symptom index and refined multivariate panel had improved accuracy in predicting ovarian cancer for patients undergoing surgery for a pelvic mass.
22	Adherence to a Practice Guideline Is Associated With Reduced Referral Time to Treating Physician (Gynecologic Oncologist)	Boac, et al., AJOG	2018	N=335	Patients whose workup adhered to the 4 NCCN-based categories were seen by the gynecologic oncologist in a significantly shorter time. This work identified several areas for improvement in the care of OVCA patients, including utilization of physician referrals and tumor markers.

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. In September 2017, Allied Market Research, a market research and business consulting partnership, published a study that forecasts IVD market revenue will reach $84 billion by 2023. 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 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 2019 , 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, Stage 1A, the patient has a 5-year survival rate of 94%. Ovarian cancer patients have up to a 90% 5-year survival 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 long-term survival from the disease, another factor that predicts clinical outcomes 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

Starting in 2014, we offered OVA1 via ASPiRA LABS. In March 2015, we 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-o wned subsidiary, ASPiRA LABS. Pursuant to this agreement as amended as of March 1, 20 18 , Quest Diagnostics has continued to provide blood draw and logistics support by transporting specimens to ASPiRA LABS for testing in exchange for a market value fee. Per the terms of the agreement, we may not offer to existing or future Quest Diagnostics customers CA 125II or other tests that Quest Diagnostics offers. As of the date of this Annual Report on Form 10-K, we are in the process of renewing this agreement.

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, since 2016, solely 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.

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 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 March 2015, we announced that OVA1 was CE marked, a requirement for marketing the test in the European Union . 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 could begin marketing Overa and OVA1 outside the United States in 2017.

Approximately 7,679 OVA1 tests were performed in 2018 compared to 8,575 in 2017 , with the decrease being attributed to the loss of a large reference laboratory account in July 2017 , partially offset by new contracts . In 2018 , we continued to develop the market through experienced market development specialists and customer account managers and hired new Regional 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, despite gains in positive medical policy coverage and contract agreements, insurance coverage and patient bills remain a concern to the physician and can disrupt the ordering pattern of a generalist who is supportive of OVA1. We have instituted a “Patient Advocacy Program” to assist with this process to proactively assess insurance and educate patients on testing costs prior to testing being performed.

Reimbursement

In the United States, revenue for diagnostic tests comes from several sources, including third-party payers such as insurance companies, government healthcare programs, such as Medicare and Medicaid, client bill accounts and patients. Novitas Solutions, a Medicare contractor, covers and reimburses for OVA1 tests performed in certain states, including Texas. Because OVA1 tests are exclusively performed at ASPiRA LABS in Texas, this local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans . ASPiRA LABS also bills third-party commercial and other government payers as well as client bill accounts and patients for OVA1.

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 "). In November 2017, we announced that the CMS released the Final 2018 Clinical Lab Fee Schedule ("CLFS"), effective January 1, 2018. Under the new fee schedule, the price for OVA1(MIA) (code 81503) is $897. This is a four-fold increase over the previous CMS rate, and this new rate was based on the median of private payer payments submitted to CMS by companies, including ASPiRA Labs, as part of the market-based payment reform mandated through PAMA. The rate is scheduled to be in effect for a three-year term from January 2018 through December 2020.

CMS also published a final price for Overa of $950, which was benchmarked to the only proteomic test currently on the CLFS that uses biomarkers and an algorithm to produce a prognostic score. The rate is scheduled to be in effect for a three-year term from January 2018 through December 2020.

Starting in 2016, we were able to make progress in achieving positive medical policy and/or payer contracts. We have continued to make progress with increased payer positive medical polices for an estimated total of over 151 million covered lives as of December 31, 201 8 . This represents an increase from an estimated 125 million covered lives as of March 1, 2018 .

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 federally registered trademarks for *Vermillion, OVA1, Overa* and *OvaCalc* and a portfolio of owned, co-owned or licensed patents and patent applications. As of the date of the filing of this Annual Report on Form

10-K , our clinical diagnostics patent portfolio included 2 1 issued United States patents, 7 pending United States patent applications, and numerous pending patent applications and issued patents outside the United States. These patents and patent applications fall into 24 patent families and are directed to diagnostic technologies.

Our research collaboration agreement with JHU expired in March 2016. There were no collaboration expenses under the JHU collaboration agreement for the year s ended December 31, 2018 and December 31, 2017 under the collaboration agreement . U nder the terms of our amended license agreement with JHU dated September 19, 2016 , 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.

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 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. In March 2015, OVA1 was CE marked, a requirement for marketing the test in the European Union. In October 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union.

Employees

As of December 31, 2018 , we had 43 full-time employees. We also engage independent contractors from time to time.

Code of Ethics for Executive Officers

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

Corporate Information

We were originally incorporated in 1993, and we had our initial public offering in 2000. Our executive offices are located at 12117 Bee Caves Road, Building Three, Suite 100, Austin, Texas 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.

The SEC 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

There is substantial doubt about our ability to continue as a going concern, and this may adversely affect our stock price and our ability to raise capital.

We have incurred significant losses and negative cash flows from operations since inception and have an accumulated deficit of nearly $ 407 million as of the end of the period covered by this report. The Company also expects to incur a net loss and negative cash flows from operations in 2019 . Given these conditions, there is substantial doubt about the Company's ability to continue as a going concern and our independent registered public accounting firm's report on our financial statements for the year ended December 31, 2018 includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern given our recurring net losses and negative cash flows from operations.

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, 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, distribution 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.

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 2019 . Our losses have resulted principally from costs incurred in cost of revenue, sales and marketing, general and administrative costs and research and development. The number of OVA1 tests performed in 2016, 2017 and 2018 was 9,125 , 8,575, and 7,679 , respectively. If we are unable to increase the volume of OVA1 sales, our business, results of operations and financial condition will be adversely affected.

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.

We are responsible for obtaining payment from third-party payers. 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. While CMS has issued PAMA reimbursement rates for OVA1 and Overa effective January 1, 2018, there is no guarantee that CMS will continue to cover the OVA1 test or that the payment rate will be comparable to the PAMA rate. 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 will 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 will 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, distribution or other operations on the scope or scale of our current activity.

Failure to meet Nasdaq's continued listing requirements could result in the delisting of Vermillion common stock, negatively impact the price of Vermillion common stock and negatively impact our ability to raise additional capital.

On July 24, 2018, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that, for the preceding 30 consecutive business days, the closing bid price for Vermillion common stock was below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). On January 22, 2019, Vermillion was granted an additional 180-calendar day compliance period to regain compliance with the minimum bid price requirement, and in March 2019, we regained compliance. There is no assurance that we will maintain compliance with this or any of the other Nasdaq continued listing requirements.

If, in the future, we fail to comply with Nasdaq's continued listing requirements, Vermillion common stock will be subject to delisting. If that were to occur, Vermillion common stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell Vermillion securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in Vermillion common stock. This would adversely affect the ability of investors to trade Vermillion securities and would adversely affect the value and liquidity of Vermillion common stock. These factors could contribute to lower prices and larger spreads in the bid and ask prices for Vermillion common stock. If we seek to implement a reverse stock split in order to remain listed on The Nasdaq Capital Market, the announcement or implementation of such a reverse stock split could negatively affect the price of Vermillion common stock.

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.

In 2017 and 2018 , virtually all of our product revenue was generated in the United States. If we are able to successfully commercialize OVA1 and Overa outside the United States, there are risks inherent in conducting business internationally, including the following:

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

If we 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 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/or 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 or Overa in efficacy but is priced at a lower point, we and/or our strategic partners may have to lower the price of OVA1 or 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 seven 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 could 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.

For example, one of the five immunoassay component kits that are used in OVA1 has 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 a 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.

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, 2019). PAMA halted certain reductions in payment mandated by the PPACA as well as certain CMS policies and has instead established a market-based reimbursement system for clinical laboratories beginning in 2018 after requiring reporting of certain private payer reimbursement data by laboratories. 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.

T he current presidential administration and U.S. Congress has made efforts to delay, modify or repeal certain provisions of the Affordable Care Act. In December 2017, the House and Senate passed a new tax bill effective January 1, 2019 that ended the individual mandate , a tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage . The passage of this bill could result in increased premiums and result in fewer covered individuals. This and other 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 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 perform OVA1 testing 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. The FDA has not finalized its October 2014 draft guidance documents that outline the FDA's proposal to actively regulate LDTs and instead on January 13, 2017 released a Discussion Paper on LDTs. The FDA's efforts to achieve broad regulation of LDTs appear to be on hold until a change in administration.

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. Instead, CMS oversees clinical laboratory operations through the Clinical Laboratory Improvement Amendments ("CLIA") program.

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. The 2017 Discussion Paper makes recommendations on what the agency would like to see better-controlled. However, it does not have the force of law, and it is not a guidance document.

Even without any new 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.

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 and ASPiRA LABS 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 and ASPiRA LABS 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 and ASPiRA LABS 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.

We selectively explore acquisition opportunities and strategic alliances relating to other businesses, products or technologies. We may not be successful in integrating other businesses, products or technologies with our business. Any such transaction also may not produce the results we anticipate, which could adversely affect our business, financial condition and results of operations.

We selectively explore and may pursue acquisition and other opportunities to strengthen our business and grow our company. We may enter into business combination transactions, make acquisitions or enter into strategic partnerships, joint ventures or alliances, any of which may be material. The market for acquisition targets and strategic alliances is highly competitive, which could make it difficult to find appropriate merger or acquisition opportunities. If we are required to raise capital by incurring debt or issuing additional equity for any reason in connection with a strategic acquisition or investment, financing may not be available or the terms of such financing may not be favorable to us and our stockholders, whose interests may be diluted by the issuance of additional stock.

The process of integration may produce unforeseen regulatory issues and operating difficulties and expenditures and may divert the attention of management from the ongoing operation of our business and harm our reputation. We may not successfully achieve the integration objectives, and we may not realize the anticipated cost savings, revenue growth and synergies in full or at all, or it may take longer to realize them than expected, any of which could negatively impact 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. Our stock issuances since May 2013 have primarily 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 recently as February 13, 2019, five persons, in aggregate, beneficially owned approximately 45.9 million shares of our common stock, including the right to acquire approximately 2.7 million shares under warrant or option agreements. The shares of common stock currently held by these individuals, excluding the right to acquire those shares under warrant or option agreements, represent 57% of our outstanding shares of common stock. 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, 2018 , we had 75,501,394 shares of our common stock outstanding and 5,178,819 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 4,612,005 shares of our common stock that were subject to outstanding options.

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. On April 17, 2018, the Company completed two public offerings, pursuant to which certain investors purchased Vermillion common stock and Vermillion Series B convertible preferred stock for net proceeds of approximately $13,500,000 after deducting offering expenses.

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

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	January 31, 2020
Trumbull, Connecticut	10,681 sq. ft.	Administrative offices and ASPiRA IVD laboratory facility	June 7, 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 4, 2019 , there were 9 0 registered holders of record of our common stock. The closing price of our common stock on March 2 1 , 201 9 was $1. 35 .

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 continued to administer the 2000 Plan with respect to the stock options that remain ed outstanding under the 2000 Plan . All remaining options expired during 2018. At December 31, 2018 , there were no options to purchase shares of Vermillion's common stock that 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 12 ,122,983 shares of Vermillion's common stock under the 2010 Plan, subject to adjustment as provided in the 2010 Plan. At December 31, 2018 , options to purchase 4, 612,005 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 the 2010 Plan as of December 31, 2018 , 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	4,612,005	$ 1.67	5,178,819
Equity compensation plans not approved by security holders	-	-	-
Total	4,612,005		5,178,819

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

We aim to serve as a diagnostic service and bio-analytic solutions provider, and we plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders.

We believe 2019 will be a transformative year for Vermillion as we continue to roll-out our new generation of technology, new decentralized and evolving web-service platform, CA125 ethnic disparity gap awareness, and full commercial strategy, all of which began in the fourth quarter of 2018.

In the fourth quarter of 2018, we launched our new generation of technology, OVA1+. OVA1+ is designed to improve accuracy and reduce false positives by nearly 40% by leveraging the strengths of OVA1's sensitivity and Overa's specificity. OVA1+ will also be available through a decentralized platform structure enabling hospital networks and super groups to run the test in their labs.

Also in the fourth quarter, we presented CA125 Disparity data at Mid-Atlantic Gynecologic Oncology Society and submitted an abstract and manuscript for national publication.

We are focused on commercializing OVA1 and Overa both inside and outside the U.S. In 2018, we established medical and advisory support and a Key Opinion Leader Network aligned with our territories in the U.S. In addition, we added to our direct sales force in late 2018 and into the first quarter of 2019, and we put OVA1 on a global testing platform (like we had done with Overa), which allows tests to be deployed internationally as well as run locally in the United States at major customer sites. In 2019, we plan to more fully commercialize OVA1 and Overa by utilizing select laboratories for distribution, managed care coverage in select markets, our sales force and our existing customer base. We also plan to develop an LDT product series, which we refer to internally as Diagnostic Algorithms #1 ("DxA1") and Diagnostic Algorithms #2 ("DxA2"). We anticipate that DxA1 and DxA2 will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value.

Carrying this into the first quarter, we entered into a comprehensive study agreement with Clalit Health Services to validate OVA1 (MIA), OVERA® (MIA2G) and OVA1+ on the Israeli population. Vermillion's technology will be studied on this high risk BRCA population to determine if earlier stage disease can be diagnosed and if the time to surgical treatment can be expedited for improved surgical outcomes for patients with an adnexal mass.

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

Prior to January 1, 2018, we recognized product revenue in accordance with the provisions of ASC 954-605, *Health Care Entities - Revenue Recognition* . Our product revenue is generated by performing diagnostic services using its OVA1 and Overa tests, and the service is completed upon the delivery of the test result to the prescribing physician. Under the previous revenue recognition accounting methodology, certain product revenue was recognized upon the ultimate receipt of cash. Under ASC Topic 606, *Revenue from Contracts with Customers* (" ASC 606"), all revenue is recognized upon completion of the OVA1 or Overa test based on estimates of amounts that will ultimately be realized. In determining the amount to accrue for a delivered test result, we consider factors such as historical payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and us, and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management. We also reviewed our patient account population and determined an appropriate distribution of patient accounts by payer (*i.e.* , Medicare, patient pay, other third-party payer, *etc* .) into portfolios with similar collection experience. When evaluated for collectability, this results in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on an individual contract basis.

Under the modified retrospective implementation method, we recorded a one-time cumulative effect adjustment at January 1, 2018 to reflect the aggregate effect of all OVA1 and Overa tests performed prior to January 1, 2018 as if revenue had been recognized

under ASC 606. The cumulative effect adjustment was recorded increasing the opening balance of Accounts Receivable by $500,000 in the condensed consolidated balance sheets with an offsetting reduction to Accumulated Deficit.

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 our historical volatility in deriving the expected volatility assumption. We made an assessment that our historic volatility is most representative of future stock price trends. 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.

Liquidity

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 State of Connecticut Department of Economic and Community Development (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, as amended, 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 by March 1, 2021 (the "Measurement Date"). Conversely, if we are either unable to meet these job creation and retention milestones, namely, hiring and retaining for a consecutive two-year period 40 full-time employees with a specified average annual salary by the Measurement Date, 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 plus a penalty of 5% of the total funded l oan.

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 other 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 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 .

As discussed in Note 7, on August 31, 2017, certain investors exercised outstanding warrants to purchase shares of Vermillion common stock for net proceeds of approximately $3,57 6 ,000 after deducting offering expenses.

As discussed in Note 7, on April 17, 2018, the Company completed two public offerings, pursuant to which certain investors purchased Vermillion common stock and Vermillion Series B convertible preferred stock for net proceeds of approximately $13,500,000 after deducting offering expenses.

We have incurred significant net losses and negative cash flows from operations since inception, and as a result have an accumulated deficit of approximately $ 406,924 ,000 at December 31, 2018 . The Company expects to incur a net loss in 2019 as wel l. In order to continue our operations as currently planned through 2019 and beyond, we will need to raise additional capital. Given the

above conditions, there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

We expect to raise capital through a variety of sources, which may include the exercise of common stock warrants, (*e.g.* , the warrants to purchase 2,810,338 shares of Vermillion common stock at $1.80 per share, which warrants were issued in February 2017 and expire in February 2022 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), 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 we are unable to obtain additional capital, we 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 our business, results of operations and financial condition.

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 .

Recent Developments

On July 24, 2018, the Company received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying the Company that, for the preceding 30 consecutive business days, the closing bid price for the Company's common stock was below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). On January 22, 2019, Vermillion was granted an additional 180-calendar day compliance period to regain compliance with the minimum bid price requirement. On March 22, 2019, we achieved compliance with Nasdaq's continued listing requirements after the closing bid price of Vermillion common stock was at least $1.00 per share for 10 consecutive business days. However, there is no assurance that we will maintain compliance with this or any of the other Nasdaq continued listing requirements. Results of Operations – Year Ended December 31, 2018 as compared to Year Ended December 31, 2017

The Company's selected summary financial and operating data for the years ended December 31, 2018 and 2017 were as follows:

	Year Ended December 31,		Increase (Decrease)	
(dollars in thousands)	2018	2017	Amount	%
Revenue:				
Product	$ 2,772	$ 2,853	$ (81)	(3)
Service	281	268	13	5
Total revenue	3,053	3,121	(68)	(2)
Cost of revenue:				
Product	2,044	1,756	288	16
Service	1,098	1,158	(60)	(5)
Total cost of revenue	3,142	2,914	228	8
Gross profit / (loss)	(89)	207	(296)	(143)
Operating expenses:				
Research and development	550	837	(287)	(34)

Sales and marketing	5,642	4,268	1,374	32
General and administrative	5,052	5,543	(491)	(9)
Total operating expenses	11,244	10,648	596	6
Loss from operations	(11,333)	(10,441)	(892)	9
Interest (expense) / income, net	(22)	(42)	20	(48)
Other (expense) / income, net	(16)	(14)	(2)	14
Net loss	$ (11,371)	$ (10,497)	$ (874)	8

Product Revenue . Product revenue was approximately $2, 772 ,000 for the year ended December 31, 2018 compared to $2, 853 ,000 for the same period in 2017 . Effective January 1, 2018, revenue for ASPiRA LABS is being recognized when the OVA1 test is being performed based on estimates of what we expect to ultimately realize. The 3% product revenue decrease is due to a decrease in tests performed compared to the prior year , especially those for client bill customers .

The number of OVA1 tests performed decreased 10 % to 7,679 OVA1 tests during the year ended December 31, 2018 compared to 8,575 OVA1 tests for the prior year. The volume decrease was primarily due to the previously announced loss of a client bill customer in July 2017, which was concentrated in uncovered territories (territories not covered by an ASPiRA sales representative). Partially offsetting the volume decrease was year-over-year growth in covered territories (territories covered by an ASPiRA sales representative).

Service Revenue. Service revenue was $ 281 ,000 for the year ended December 31, 2018 compared to $ 268 ,000 for the same period in 201 7, a n increase of $ 13 ,000, or 5 %. Service revenue will vary from quarter to quarter based on the size of ongoing customer projects. Revenue for ASPiRA IVD is being recognized once certain revenue recognition criteria have been met (see Note 1 to the financial statements included in Part II, Item VIII of this Form 10-K).

Cost of Revenue - Product. Cost of product revenue was $ 2,044 ,000 for the year ended December 31, 2018 compared to $1 ,756 ,000 for the same period in 2017 , representing a n in crease of $ 288 ,000, or 16 %, due primarily to some equipment maintenance costs, increased shipping costs as well as Quest project management fees incurred in 2018 .

Cost of Revenue - Service. Cost of service revenue was $1, 09 8,000 for the year ended December 31, 201 8 compared to $ 1,158 ,000 for the same period in 2017 . The decrease of 5% was primarily due to a decrease in headcount and consulting, offset by lab supplies

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 decreased by $ 287 ,000, or 34 %, for the year ended December 31, 2018 compared to the same period in 2017 . This decrease was mainly due to decreases in consulting costs . In 2018 , we internally performed ongoing product pipeline development at a lower cost, including patient consents under IRB for our pelvic mass specimen and data repository and cataloguing of serum samples for future research purposes. We expect research and development expenses in 2019 to increase compared to those of 2018, due to some new tests being developed .

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 increased by $ 1,374 ,000, or 32 %, for the year ended December 31, 2018 compared to the prior year. This increase was primarily due to a n increase in personnel and personnel expenses as well as consulting costs . We expect sales and marketing expenses to increase in future periods as we expand our sales team in specific markets where we have broad payer coverage and key opinion leader support.

General and Administrative Expenses . General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses, and other infrastructure expenses. General and administrative expenses decreased by $ 491 ,000, or 9 %, for the year ended December 31, 2018 compared to the same period in 2017 . The decrease was primarily due to o ne -time charges for Senior Vice President & Chief Accounting Officer severance as well as non-cash stock compensation i n 2017 , partially offset by increased consulting costs . We expect general and administrative expenses in 2019 to increase modestly over those of 2018 .

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.

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, as amended, 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 by March 1, 2021 (the "Measurement Date"). Conversely, if we are either unable to meet these job creation and retention milestones, namely, hiring and retaining for a consecutive two-year period 40 full-time employees with a specified average annual salary by the Measurement Date 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 plus a penalty of 5% of the total funded l oan. 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 other 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 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 . The Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2018 , we had an accumulated deficit of $ 406,924 ,000 and stockholders' equity of $ 7,152 ,000. On December 31, 2018 , we had $ 9,360 ,000 of cash and cash equivalents and $2, 964 ,000 of current liabilities. The Company expects to incur a net loss in 2019 as well. Working capital levels are not sufficient to fund operations as currently planned through 2019 and beyond, absent a significant increase in revenue over historic revenue or additional financing . Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern.

As discussed in Note 7, on August 31, 2017, certain investors exercised outstanding warrants to purchase shares of Vermillion common stock for net proceeds of approximately $3,576,000 after deducting offering expenses.

As discussed in Note 7, on April 17, 2018, the Company completed two public offerings, pursuant to which certain investors purchased Vermillion common stock and Vermillion Series B convertible preferred stock for net proceeds of approximately $13,500,000 after deducting offering expenses. The Series B convertible preferred stock was converted to common stock on June 21, 2018.

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 2019 .

Our management 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 offerings, debt financing, collaborations, licensing arrangements, grants and government funding and strategic alliances.

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 OVA1 and Overa adoption by physicians and patients;
- the insurance payer community's acceptance of and reimbursement for OVA1 and Overa;
- the successful targeted launch of Overa;
- resources devoted to our IVD trials laboratory and services;
- the revenue generated by our IVD trial services business;

- our plans to acquire or invest in other products, technologies and businesses; and
- the market price of our common stock;

Cash and cash equivalents as of December 31, 2018 and December 31, 201 7 were $ 9,360 ,000 and $5, 539 ,000, respectively. At December 31, 2018 and 2017 , working capital was $ 7,824 ,000 and $3, 696 ,000, respectively.

Net cash used in operating activities was $9,367,000 for the year ended December 31, 2018, resulting primarily from $11,371,000 net loss incurred partially offset by $1,101,000 of stock-based compensation expense , $ 675 ,000 of depreciation and amortization expense and a $380,000 increase in accrued liabilities . Net cash used in operating activities also included $ 152 ,000 of cash used from changes in operating assets and liabilities.

Net cash used in operating activities was $8,129,000 for the year ended December 31, 2017, resulting primarily from $10,497,000 net loss incurred partially offset by $1,439,000 of stock-based compensation expense and $786,000 of depreciation and amortization expense.

Net cash used in investing activities was $113,000 for the year ended December 31, 2018, and $60,000 for the year ended December 31, 2017 due to purchases of property and equipment.

Net cash provided by financing activities was $13,301,000 for the year ended December 31, 2018, which consisted primarily of net proceeds from our April 2018 public offering of preferred and common stock.

Net cash provided by financing activities was $8,486,000 for the year ended December 31, 2017, which consisted primarily of net proceeds from our February 2017 offering of common stock and warrants totaling $5,127,000 and the August 2017 exercise of repriced warrants totaling $3,576,000.

Off-Balance Sheet Arrangements

As of December 31, 2018 , we had no off-balance sheet arrangements.

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, 2018 and 2017 , consolidated statements of operations for the years ended December 31, 2018 and 2017 , consolidated statements of changes in stockholders' equity for the years ended December 31, 2018 and 2017 , consolidated statements of cash flows for the years ended December 31, 2018 and 2017 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 Chief 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 Financial 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, 2018 .

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2018 , 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, 2018 . Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("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, 2018 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, 2018 , 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.

During the quarter ended December 31, 2018, we upgraded to Sage IntAcct, a n accounting and financial reporting software on a hosted platform. As a result of the new software, some of our internal controls were adapted to cover the same risks . Except for the changes due to the new software, there was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2018 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 “Election of Directors,” "Corporate Governance," "Management" and "Section 16(a) Beneficial Ownership Reporting Compliance," of our proxy statement relating to our annual meeting of stockholders to be held in 2019 (the “ 2019 Proxy Statement”) is incorporated by reference.

Our code of ethics is applicable to all employees, including both our Chief Executive Officer and Chief 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," "Compensation Discussion and Analysis - Executive Officer Compensation," "Corporate Governance – Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" of the 2019 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 2019 Proxy Statement is incorporated by reference.

The equity compensation plan information contained in Part II Item 5 of this Form 10-K is incorporated by reference.

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

The information appearing under the headings “Certain Relationships and Related Transactions” and "Corporate Governance" of the 2019 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 2019 Proxy Statement is incorporated by reference.

PART IV

ITEM 15. EXHIBITS, 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.

(b) EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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 and Restated Certificate of Incorporation, effective June 19, 2014	10-Q	001-34810	3.2	August 14, 2014	
3.3	Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock	8-K	001-34810	4.1	April 17, 2018	
3.4	Fifth Amended and Restated Bylaws of Vermillion, Inc., 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 dated May 8, 2013, by and among Vermillion, Inc. and the purchasers identified therein,	8-K	001-34810	10.1	May 14, 2013	
4.3	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	
4.4	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	
4.5	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	
4.6	Form of Warrant, issued February 13, 2017	8-K	001-34810	99.1	February 17, 2017	
4.7	Form of Letter Agreement, by and between Vermillion, Inc. and certain warrant holders	8-K	001-34810	4.1	August 28, 2017	
4.8	Form of Indenture	S-3	333-221092	4.6	October 24, 2017	
10.1	Vermillion, Inc. 2010 Stock Incentive Plan #	8-K	000-31617	10.1	February 12, 2010	
10.2	Ciphergen Biosystems, Inc. 401(k) Plan #	10-K	000-31617	10.7	March 22, 2005	
10.3	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	
10.4	Vermillion, Inc. Amended and Restated 2010 Stock Incentive Plan #	8-K	001-34810	10.1	December 17, 2013	
10.5	Vermillion, Inc. Second Amended and Restated 2010 Stock Incentive Plan #	8-K	001-34810	10.1	June 22, 2015	
10.6	Vermillion Inc. Second Amended and Restated 2010 Stock Incentive Plan (as amended effective June 21, 2018) #	8-K	001-34810	10.1	June 27, 2018	
10.7	Form of Vermillion, Inc.'s Stock Option Award #					√
10.8	Form of Vermillion, Inc.'s Restricted Stock Award #					√
10. 9	Employment Agreement between Vermillion, Inc. and Fred Ferrara dated April 1, 2015 #	8-K	001-34810	10.1	April 6, 2015	
10. 10	Employment Agreement between Vermillion, Inc. and Valerie B. Palmieri effective January 1, 2015 #	8-K	001-34810	99.1	December 17, 2014	
10. 11	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	

10.1 2	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	
10.1 3	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	
10.1 4	Amendment No. 3 to Testing and Services Agreement, executed as of March 1, 2018 by and among Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated	8-K	001-34810	10.1	March 6, 2018	
10.1 5	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	
10.1 6	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	
10.1 7	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	
10.1 8	Employment Agreement between Vermillion, Inc. and Robert Beechey dated December 18, 2017 #	8-K	001-34810	10.1	December 20, 2017	
10. 19	First Amendment to the Assistance Agreement by and between the State of Connecticut, acting by and through the Department of Economic and Community Development and Vermillion, Inc. dated March 7, 2018	10-K	001-34810	10.21	March 13, 2018	
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 Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√
32.0	Certification of the Chief Executive Officer and Chief Financial 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 contract 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.

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Vermillion, Inc. (the "Company") and subsidiaries as of December 31, 2018 and 2017 , the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017 , and the results of their operations and their cash flows for the years then ended **,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has net cash flows deficiencies that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.
Austin, Texas
March 28 , 2019

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

	December 31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 9,360	$ 5,539
Accounts receivable	786	205
Prepaid expenses and other current assets	550	459
Inventories	92	102
Total current assets	10,788	6,305
Property and equipment, net	608	1,181
Other assets	12	11
Total assets	$ 11,408	$ 7,497
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 950	$ 745
Accrued liabilities	1,825	1,650
Short-term debt	189	185
Other current liabilities	-	29
Total current liabilities	2,964	2,609
Long-term debt	1,292	1,481
Other non-current liabilities	-	-
Total liabilities	4,256	4,090
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, 2018 and 2017	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized; 75,501,394 and 60,036,017 shares issued and outstanding at December 31, 2018 and 2017, respectively	75	60
Additional paid-in capital	414,001	399,400
Accumulated deficit	(406,924)	(396,053)
Total stockholders' equity	7,152	3,407
Total liabilities and stockholders' equity	$ 11,408	$ 7,497

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,	
	2018	**2017**
Revenue:		
Product	$ 2,772	$ 2,853
Service	281	268
Total revenue	3,053	3,121
Cost of revenue: [1]		
Product	2,044	1,756
Service	1,098	1,158
Total cost of revenue	3,142	2,914
Gross profit / (loss)	(89)	207
Operating expenses:		
Research and development [2]	550	837
Sales and marketing [3]	5,642	4,268
General and administrative [4]	5,052	5,543
Total operating expenses	11,244	10,648
Loss from operations	(11,333)	(10,441)
Interest (expense) income, net	(22)	(42)
Other (expense) / income, net	(16)	(14)
Net loss	$ (11,371)	$ (10,497)
Deemed dividend on warrant repricing	-	(942)
Net loss attributable to common stockholders	$ (11,371)	$ (11,439)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.16)	$ (0.20)
Weighted average common shares used to compute basic and diluted net loss per common share	70,085,842	56,943,596
Non-cash stock-based compensation expense included in expenses:		
(1) Cost of revenue	$ 124	$ 136
(2) Research and development	6	9
(3) Sales and marketing	102	160
(4) General and administrative	869	1,134

See accompanying Notes to Consolidated Financial Statements

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

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2016	-	$ -	52,328,492	$ 52	$ 389,266	$ (385,556)	$ 3,762
Net loss	-	-	-	-	-	(10,497)	(10,497)
Common stock and warrants issued in conjunction with private placement sale, net of $470 in issuance costs	-	-	3,747,125	4	5,123	-	5,127
Common stock issued in conjunction with exercise of warrants, net of $220 in issuance costs	-	-	3,796,818	4	3,572	-	3,576
Common stock issued for restricted stock awards	-	-	163,582	-	335	-	335
Stock compensation charge	-	-	-	-	1,104	-	1,104
Balance at December 31, 2017	-	$ -	60,036,017	$ 60	$ 399,400	$ (396,053)	$ 3,407
Net loss	-	-	-	-	-	(11,371)	(11,371)
ASC 606 Adjustment to retained earnings	-	-	-	-	-	500	500
Common stock issued in conjunction with public offering, net of $1,008 in issuance costs	-	-	10,000,000	10	8,980	-	8,990
Preferred stock issued in conjunction with public offering, net of $504 in issuance costs	50,000	-		-	4,496	-	4,496
Preferred stock converted to common stock	(50,000)	-	5,000,000	5	(5)	-	-
Common stock issued for restricted stock awards	-	-	432,877	-	438	-	438
Common stock issued in conjunction with exercise of stock options	-	-	32,500	-	29	-	29
Stock compensation charge	-	-	-	-	663	-	663
Balance at December 31, 2018	-	$ -	75,501,394	$ 75	$ 414,001	$ (406,924)	$ 7,152

See accompanying Notes to Consolidated Financial Statements

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

	Year Ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (11,371)	$ (10,497)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	675	786
Stock-based compensation expense	1,101	1,439
Loss on sale and disposal of property and equipment	11	4
Changes in operating assets and liabilities:		
Accounts receivable	(81)	70
Prepaid expenses and other assets	(92)	28
Inventories	10	(9)
Accounts payable, accrued liabilities and other liabilities	380	50
Net cash used in operating activities	(9,367)	(8,129)
Cash flows from investing activities:		
Purchase of property and equipment	(113)	(60)
Net cash used in investing activities	(113)	(60)
Cash flows from financing activities:		
Proceeds from private placement offering of common stock and warrants, net of issuance costs	-	5,127
Proceeds from exercise of common stock warrants, net of issuance costs	-	3,576
Proceeds from public offering of preferred stock, net of issuance costs	4,496	-
Proceeds from public offering of common stock, net of issuance costs	8,990	-
Principal repayment of DECD loan	(185)	(183)
Repayment of capital lease obligations	(29)	(34)
Proceeds from issuance of common stock from exercise of stock options	29	-
Net cash provided by financing activities	13,301	8,486
Net increase in cash and cash equivalents	3,821	297
Cash and cash equivalents, beginning of year	5,539	5,242
Cash and cash equivalents, end of year	$ 9,360	$ 5,539
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	44	47
Supplemental disclosure of non-cash investing and financing activities:		
Deemed dividend on warrant repricing	-	942

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 2015, the Company distributed OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics") (see Note 3). Since August 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

As discussed in Note 6, on March 22, 2016, the Company entered into a loan agreement, as amended (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 other 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. Aggregate gross proceeds of the private placement were approximately $5,597,000 (approximately $5,127,000 net of transaction costs). The warrants are exercisable for 2,810,338 shares of Vermillion common stock at $1.80 per share. The warrants 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 .

As discussed in Note 7, on August 31, 2017, certain investors exercised outstanding warrants to purchase shares of Vermillion common stock for net proceeds of approximately $3,576,000 after deducting offering expenses.

As discussed in Note 7, on April 17, 2018, the Company completed two public offerings, pursuant to which certain investors purchased Vermillion common stock and Vermillion Series B convertible preferred stock for net proceeds of approximately $13,500,000 after deducting offering expenses.

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 $406,924,000 at December 31, 2018. The Company expects to incur a net loss in 2019 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, 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. Management expects cash from product and ASPiRA IVD sales to be the Company's only material, recurring source of cash in 2019. Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

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

Virtually all 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.

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: Prior to January 1, 2018, the Company recognized product revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition. 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 the test result to the prescribing physician. The entire transaction price is allocated to the single performance obligation contained in a contract with a patient. Under the previous revenue recognition accounting methodology, certain product revenue was recognized upon the ultimate receipt of cash. Under ASC 606, all revenue is recognized upon completion of the OVA1 or Overa test based on estimates of amounts that will ultimately be realized. In determining the amount of revenue to be recognized for a delivered test result, the Company considers factors such as payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and the Company, and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management as the collection cycle on some accounts can be as long as one year.

The Company also reviewed its patient account population and determined an appropriate distribution of patient accounts by payer (*i.e.* , Medicare, patient pay, other third-party payer, *etc* .) into portfolios with similar collection experience. The Company has elected this practical expedient that, when evaluated for collectability, results in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on an individual contract basis. There were no impairment losses on accounts receivable recorded during the year ended December 31, 2018.Under the modified retrospective implementation method, the Company recorded a one-time cumulative effect adjustment at January 1, 2018 to reflect the aggregate effect of all open OVA1 and Overa tests performed prior to January 1, 2018 as if revenue had been recognized under ASC 606. The cumulative effect adjustment was recorded increasing the opening balance of Accounts Receivable by $500,000 in the condensed consolidated balance sheets with an offsetting reduction to Accumulated Deficit. The Company’s right to receive payment on this balance is contingent only on the passage of time.

The following tables show the impact of adoption to our consolidated statement of operations and balance sheet:

Twelve Months Ended December 31, 2018

(in thousands, except per share amounts)	**Impact of changes in accounting policies**		
	As Reported	**Balances without adoption of ASC 606**	**Effect of Change Higher/(Lower)**
Product revenue	$ 2,772	$ 2,731	$ 41
Operating loss	$ (11,333)	$ (11,374)	$ 41
Net loss	$ (11,371)	$ (11,412)	$ 41
Net loss per share, basic and diluted	$ (0.16)	$ (0.16)	$ -

December 31, 2018

(in thousands)	**Impact of changes in accounting policies**		
	As Reported	**Balances without adoption of ASC 606**	**Effect of Change Higher/(Lower)**
Assets:			
Accounts receivable	$ 786	$ 245	$ 541
Stockholders' equity:			
Accumulated deficit	$ (406,924)	$ (407,465)	$ 541

ASC 606 did not have an aggregate impact on the Company’s net cash provided by operating activities, but resulted in offsetting changes in certain assets and liabilities presented within net cash provided by operating activities in the Company’s consolidated statement of cash flows, as reflected in the above tables.

Other Practical Expedients

The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

The Company expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses.

Service Revenue: The Company's service revenue is generated by performing IVD trial services for third-party customers. Application of the modified retrospective method did not impact amounts previously reported by the Company, nor did it require a cumulative effect adjustment upon adoption, as the Company's method of recognizing revenue under ASC 606 was analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for the Company to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

Measurement of progress on contracts with customers will generally be based on the input measurement of cost incurred relative to the total expected costs to satisfy the performance obligation. The Company has not disclosed the value of unsatisfied performance obligations for all service revenue contracts with an original expected length of one year or less, which is an optional exemption that is permitted under the adoption rules. The remainder are not material to the consolidated financial statements.

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 general and administrative expenses on the Consolidated Statements of Operations. Such costs aggregated approximately $219,000 and $258,000 for the years ended December 31, 2018 and 2017, 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. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. The Company uses 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 actual experience with the options granted and represents the period of time that the options granted are expected to be outstanding. This data includes employees' expected exercise and post-vesting employment termination behaviors. The expected stock price volatility is estimated using Company historical volatility in deriving the expected volatility assumption . The Company made an assessment that Company historic volatility is most representative of future stock price trends. 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 the Company's 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 records stock-based compensation net of estimated forfeitures.

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, *Accounting for Uncertainty in Income Taxes* c larifies 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.

The Tax Cuts and Jobs Act (H.R. 1), was enacted on December 22, 2017. ASC740, *Accounting for Income Taxes* , requires companies to recognize the effect of tax law changes in the period of enactment even though the effective date for most provisions is for tax years beginning after December 31, 2017. Since the Company's federal deferred tax asset was fully offset by a valuation allowance, the reduction in the U.S. corporate income tax rate to 21% did not materially affect the Company's financial statements.

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 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 debt are at cost, which approximates fair value due to the short maturity of those instruments. The carrying value of debt approximates fair value due to its interest rate approximating market rates of interest available to the Company for similar instruments.

Segment Reporting

The Company's chief operating decision maker evaluates the business on a consolidated basis and therefore, the Company operates one reportable segment.

NOTE 2: Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), Compensation - Stock Compensation ("ASU 2016-09"). 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 Company adopted this standard on January 1, 2018, and the adoption did not have a material impact on the consolidated financial statements. In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Base Payment Accounting. This new guidance expands the scope of Topic 718 to include share-based payment transactions from acquiring goods and services from nonemployees, which was previously codified under Topic 505, where this change will modify the measurement requirements of nonemployee awards. This amendment is effective for annual periods after December 15, 2018. The Company is currently evaluating the impact of adoption of this standard.

In June 2016, 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 its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases* (“ASU 2016-02”) . The 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 standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Subsequently, i n July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements (“ASU 2018-11”) , which provides a number of optional pract ical expedients in transition. The Company adopted ASU 2016-02 effective January 1, 2019 and elected the package of practical expedients and the new transition approach permitted by ASU 2018-11. ASU 2018-11 allows the Company not to reassess existing identification of leases, classification of leases or any initial direct costs. T he Company has also elected to use the hindsight practical expedient . The Company has two office leases which are required to be record ed a s ROU asset s and corresponding lease liabilit ies on the balance sheet. T he Company has no short term leases with terms of less than twelve months . The Company expects to recognize ROU assets and a lease liability of less than $ 200,000 related to its leases on its consolidated balance sheet as of January 1, 2019. The Company will not have a cumulative adjustment impacting retained earnings.

In May 2014, the FASB issued ASC 606, which superseded existing revenue recognition guidance. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 effective on January 1, 2018 using the modified retrospective method. Please see the above “Revenue Recognition” section for a discussion of the Company’s revenue recognition under ASC 606.

NOTE 3: Strategic Alliance And Secured Line Of Credit with Quest Diagnostics Incorporated

In March 2015, the Company reached an agreement with Quest Diagnostics that terminated the previous Strategic Alliance 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 2015. Pursuant to this agreement, as amended as of March 1, 2018, Quest Diagnostics has continued to provide blood draw and logistics support by transporting specimens to ASPiRA LABS for testing in exchange for a market value fee. Per the terms of the commercial agreement, we may not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers. As of the date of this Annual Report on Form 10-K, we are in the process of renewing this agreemen .

Note 4: Property and Equipment

The components of property and equipment as of December 31, 2018 and 2017 were as follows **:**

	December 31,	
(in thousands)	**2018**	**2017**
Machinery and equipment	$ 1,367	$ 1,400
Demonstration equipment	39	39
Computer equipment and software	1,109	1,055
Furniture and fixtures	137	120
Leasehold improvements	706	706
Gross property and equipment	3,358	3,320
Accumulated depreciation and amortization	(2,750)	(2,139)
Property and equipment, net	$ 608	$ 1,181

Depreciation expense for property and equipment was $ 67 5 ,000 and $ 786 ,000 for the years ended December 31, 2018 and 2017 , respectively. The accumulated amortization of assets under capital lease obligations was $ 232 ,000 and the net book value of

assets under capital lease obligations was none as of December 31, 2018 . The accumulated amortization of assets under capital lease obligations was $1 93, 000 and the net book value of assets under capital lease obligations was $ 39 ,000 as of December 31, 2017 .

NOTE 5: Accrued Liabilities

The components of accrued liabilities as of December 31, 2018 and 2017 were as follows:

	December 31,	
(in thousands)	2018	2017
Payroll and benefits related expenses	$ 853	$ 867
Collaboration and research agreements expenses	366	358
Professional services	329	216
Other accrued liabilities	277	209
Total accrued liabilities	$ 1,825	$ 1,650

NOTE 6: Commitments, Contingencies and debt

As of December 31, 2018 , the annual amounts of future minimum payments under certain of the Company's contractual obligations are shown in the table below. Our operating leases consist of two office leases. The office leases require us to pay additional amounts for common area maintenance charges in addition to rent .

	Payments Due by Period						
(in thousands)	Total	2019	2020	2021	2022	2023	Thereafter
Operating Leases	$ 474	$ 278	$ 140	$ 56	$ -	$ -	$ -
Capital Leases	-	-	-	-	-	-	-
Debt Obligations	1,621	221	221	221	221	221	516
Total	$ 2,095	$ 499	$ 361	$ 277	$ 221	$ 221	$ 516

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, as amended, 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, 2021 (the "Measurement Date"). Conversely, if the Company is either unable to meet these job creation and retention milestones, namely, hiring and retaining for a consecutive two-year period 40 full-time employees with a specified average annual salary by the Measurement Date 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% of the total funded l oan .

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 other future milestones. The loan may be prepaid at any time without premium or penalty .

The balance of the DECD loan was $1, 481 ,000 and $1, 666 ,000 at December 31, 2018 and 2017 , respectively.

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, 2018 the Company's Austin, Texas lease included an annual base rent of $86,000 and annual estimated common area charges, taxes and insurance of $ 55 ,000 . The lease expires on January 31, 20 20 .

The Company's Trumbull, Connecticut lease includes an aggregate annual base rent of $32,000 and annual estimated common area charges, taxes and insurance of $95,000 . The lease expires on June 8, 2021 .

Rental expense under operating leases for the years ended December 31, 2018 and 2017 totaled $2 65 ,000 and $2 5 4,000 , respectively.

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 diseas e. This agreement expired on March 31, 2016. There were no collaboration expenses under the JHU collaboration agreement for the year s ended December 31, 2018 and December 31, 2017 . U nder the terms of the amended license agreement dated September 19, 2016 , 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, 2018 and 2017 totaled $1 20 ,000 and $ 116 ,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

2018 Offerings

On April 13, 2018, the Company entered into two underwriting agreements (each, an "Underwriting Agreement") with Piper Jaffray & Co., as the sole underwriter (the "Underwriter"), in connection with separate but concurrent public offerings of the Company's securities.

Pursuant to the first Underwriting Agreement, the Company agreed to issue and sell an aggregate of 10,000,000 shares of Vermillion common stock, par value $0.001 per share, offered by the Underwriter in a public offering at a price to the public of $1.00 per share (the "Common Stock Offering"). Under this Underwriting Agreement, the Company granted the Underwriter an option to purchase up to an additional 1,500,000 shares of Vermillion common stock at the public offering price, less underwriting discounts and commissions, to cover over-allotments, if any. The Underwriter did not exercise this option. The Common Stock Offering closed on April 17, 2018 and resulted in proceeds, net of 7% underwriting costs and other offering costs, to the Company of $8,992,000 .

Pursuant to the second Underwriting Agreement, the Company agreed to issue and sell an aggregate of 50,000 shares of Vermillion Series B Convertible Preferred Stock, par value $0.001 per share, offered by the Underwriter in a public offering at a price to the public of $100.00 per share (the "Series B Offering"). The Series B Offering closed on April 17, 2018 and resulted in proceeds, net of 7% underwriting costs and other offering costs, to the Company of $4,496,000 .

Upon obtaining Company stockholder approval at the annual meeting of Company stockholders on June 21, 2018, each of the 50,000 shares of Vermillion Series B Convertible Preferred Stock was automatically converted into shares of Vermillion common stock, at a conversion rate of 100 shares of Vermillion common stock per one share of Vermillion Series B Convertible Preferred Stock, including shares issuable pursuant to customary anti-dilution provisions.

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 $5,127,000 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 $4,323,000 .

Stock holder s Agreement

In connection with a private placement offering of common stock and warrants the Company completed in May 2013, the Company 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, th is stockholders agreement prohibits the Company 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.

Warrants

Warrants outstanding as of December 31, 201 8 and 2017 were as follows:

		Exercise Price	Number of Shares Outstanding under Warrant	
Issuance Date	**Expiration Date**	**per Share**	**December 31, 2018**	**December 31, 2017**
February 17, 2017	February 17, 2022	$ 1.80	2,810,338	2,810,338
			2,810,338	2,810,338

NOTE 8: Loss Per Share

The reconciliation of the numerators and denominators of basic and diluted loss per share for the years ended December 31, 201 8 and 2017 was as follows:

(In thousands, except per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
Year ended December 31, 2017:			
Net loss	$ (10,497)		
Deemed dividend on warrant repricing	(942)		
Net loss available to common shareholders - basic	(11,439)	56,943,596	$ (0.20)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards	-	-	
Net loss available to common shareholders - diluted	$ (11,439)	56,943,596	$ (0.20)

Year ended December 31, 2018:				
Net loss available to common shareholders - basic	$ (11,371)	70,085,842	$	(0.16)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards	-	-		
Net loss available to common shareholders - diluted	$ (11,371)	70,085,842	$	(0.16)

Due to net losses for the years ended December 31, 2018 and 2017 , 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, 2018 and 2017 were as follows:

	Year Ended December 31,	
	2018	**2017**
Stock options	4,612,005	4,219,568
Stock warrants	2,810,338	2,810,338
Unvested restricted stock awards	11,667	1,704
Potential common shares	7,434,010	7,031,610

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 s ended December 31, 2018 or 2017 . All remaining options expired during 2018. 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. In June 2015 and June 20 1 8 , Vermillion's stockholders approved increase s of 4,500,000 and 4,000,000, respectively , in the number of shares available for issuance under the 2010 Plan for a total of 12 ,122,983 shares. Unexercised options generally expire ten years from the date of grant. Options to purchase 32,500 shares of common stock were exercised during the year ended December 31, 2018. There were no options exercised during the year ended December 31, 2017. During the year ended December 31, 2018 , Vermillion issued to Vermillion's Board of Directors an aggregat e of 398,400 shares of restricted stock under the 2010 Plan having a fair value of $ 442 ,000 as payment for services rendered in 2018 . 35,000 of those shares of restricted stock were forfeited upon the departure of a board member in June. The Company also issued to certain consultants 40,606 shares of restricted stock under the 2010 Plan having a fair value of $ 32 ,000 . During the year ended December 31, 2017 , Vermillion issued to Vermillion's Board of Directors 131,250 shares of restricted stock under the 2010 Plan having a fair value of $ 281 ,000 as payment for services rendered in 2017 . The Company also issued to certain consultants 32,332 shares of restricted stock under the 2010 Plan having a fair value of $ 54 ,000 .

The activity related to shares available for grant under the 2000 Plan and the 2010 Plan for the years ended December 31, 2018 and 2017 was as follows:

		2010 Stock Option	
	2000 Stock Plan	**Plan**	**Total**
Shares available at December 31, 2016	-	2,989,760	2,989,760
Options canceled	3,050	776,455	779,505

Reduction in shares reserved	(3,050)	-	(3,050)
Options granted	-	(1,548,000)	(1,548,000)
Restricted stock units granted	-	(163,582)	(163,582)
Shares available at December 31, 2017	-	2,054,633	2,054,633
Shares added	-	4,000,000	4,000,000
Options canceled	18,000	861,063	879,063
Reduction in shares reserved	(18,000)	-	(18,000)
Options granted	-	(1,304,000)	(1,304,000)
Restricted stock units granted	-	(432,877)	(432,877)
Shares available at December 31, 2018	-	5,178,819	5,178,819

The stock option activity under the 2000 Plan and 2010 Plan for the years ended December 31, 2018 and 2017 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Options outstanding at December 31, 2016	3,451,073	$ 1.70	$ 41	8.46
Granted	1,548,000	2.05		
Exercised	-	-		
Canceled	(779,505)	1.51		
Options outstanding at December 31, 2017	4,219,568	$ 1.86	$ 1,033	8.02
Granted	1,304,000	0.98		
Exercised	(32,500)	0.89		
Canceled	(879,063)	1.58		
Options outstanding at December 31, 2018	4,612,005	$ 1.67	$ -	7.17
Shares exercisable:				
December 31, 2018	2,391,760	$ 1.94	$ -	5.72
Shares expected to vest:				
December 31, 2018	1,820,601	$ 1.39	$ -	8.74

The range of exercise prices for options outstanding and exercisable at December 31, 2018 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		1,386,687	$ 0.97	8.78	210,687	$ 1.01
1.31	- 1.64		1,249,668	1.49	6.83	846,042	1.49
1.65	- 2.08		852,500	1.99	4.31	714,381	1.99
2.09	- 11.55		1,123,150	3.29	5.58	620,650	2.79
$ 0.01	- $ 11.55		4,612,005	$ 1.67	7.17	2,391,760	$ 1.94

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2018	$ 9	$ 2,319
Year ended December 31, 2017	$ -	$ 2,272

Stock-based Compensation

Employee Stock-based Compensation Expense

The Company records stock-based compensation net of estimated forfeitures. 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, 2018 and 2017 were as follows:

	Year Ended December 31,	
	2018	2017
Dividend yield	- %	- %
Volatility	69 %	69 %
Risk-free interest rate	2.69 %	1.77 %
Expected lives (years)	4.0	4.0
Weighted average grant date fair value	$ 0.51	$ 1.11

The allocation of employee stock-based compensation expense by functional area for the years ended December 31, 2018 and 2017 was as follows:

(in thousands)	Year Ended December 31, 2018	2017
Cost of sales	$ 91	$ 82
Research and development	6	6
Sales and marketing	112	150
General and administrative	982	914
Total	$ 1,191	$ 1,152

As of December 31, 2018 , total unrecognized compensation cost related to unvested stock option awards was approximately $ 1,540, 000 and the related weighted average period over which it is expected to be recognized was 2. 65 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, 201 8 and 201 7 , the Company did no t contribute to the 401(k) Plan.

NOTE 10: Income Taxes

There was no income tax expense or benefit for the years ended December 31, 2018 or 2017 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 its net deferred tax assets at December 31, 2018 and 2017 .

The components of net deferred tax assets at December 31, 2018 and 201 7 were as follows:

(in thousands)	Year Ended December 31, 2018	2017
Deferred tax assets:		
Net operating losses	$ 20,614	$ 17,768
Amortization - R&D intangibles	2,410	3,091
Other	2,406	2,461
Total deferred tax assets	25,430	23,320
Valuation allowance	(25,430)	(23,320)
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, 2018 and 2017 was as follows:

	Year Ended December 31, 2018	2017
Tax at federal statutory rate	21 %	34 %
State tax, net of federal benefit	1	1
Valuation allowance	(19)	74
Permanent items	-	(2)
Change in Federal Tax Rate (2017 Tax Reform)	2	(111)
Other	(5)	4
Effective income tax rate	- %	- %

As a result of the Tax Cuts and Jobs Act of 2017, net operating losses (" NOLs ") arising before January 1, 2018, and NOLs arising after January 1, 2018, are subject to different rules. The Company's pre-2018 NOLs will expire in varying amounts from 2023 through 2037, if not utilized and can offset 100% of future taxable income for regular tax purposes. Any NOLs arising after January 1, 2018 can generally be carried forward indefinitely and can offset up to 80% of future taxable income. The Company's ability to use its NOLs during this period will be dependent on its ability to generate taxable income, and the NOLs could expire before the Company generate s sufficient taxable income . The Company's ability to use net operating loss carryforwards may be restricted due to ownership change limitations occurring in the past or that could occur in the future , as required by Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state provisions. These ownership changes may also limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

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

L egislation commonly referred to as the Tax Cuts and Jobs Act (H.R. 1) was enacted on December 22, 2017. ASC740, *Accounting for Income Taxes* , requires companies to recognize the effect of tax law changes in the period of enactment even though the effective date for most provisions is for tax years beginning after December 31, 2017. Since the Company's federal deferred tax asset was fully offset by a valuation allowance, the reduction in the U.S. corporate income tax rate to 21% did not materially affect the Company's financial statements.

Provisional amounts

Deferred tax assets and liabilities: Certain domestic-related deferred tax assets and liabilities were remeasured based on the rates at which they are expected to reverse in the future, which is generally 21 percent. As a valuation allowance is recorded for the full amount of these deferred tax assets and liabilities, the remeasurement of the deferred tax assets and liabilities was offset by a corresponding remeasurement of the valuation allowance.

Company management believe s that it is more likely than not that the benefit from certain deferred tax assets will not be realized due to the history of the Company's operating losses. In recognition of this risk, the Company has provided a valuation allowance on the deferred tax assets relating to these assets. The valuation allowance was approximately $2 5 ,000,000 and $ 23 ,000,000 at December 31, 2018 and 2017 , respectively. The in crease of $ 2 ,000,000 between 2017 and 2018 is primarily due to adjustments to the domestic 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, 2018 , the Company's federal returns for the years ended 2015 through the current period and most state returns for the years ended 2014 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 2015 and 2014 , respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2017 reflect research and development carryforwards of $5, 621 ,000 and $5,3 12 ,000 , respectively. The Company has recognized additional deferred tax assets for federal and California research and development credits of $ 16 ,000 and $ 18 ,000 for the year ended December 31, 2018 , respectively.

As of December 31, 2018 , the Company's gross unrecognized tax benefits are approximately $10, 967 ,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, 2016	$ 5,430	$ 5,317	$ 10,747
Increase in tax position during 2017	46	35	81
Decrease due to expirations	-	-	-
Balance at December 31, 2017	$ 5,476	$ 5,352	$ 10,828
Return to provision true up	145	(40)	105
Increase in tax position during 2018	16	18	34
Decrease due to expirations	-	-	-
Balance at December 31, 2018	$ 5,637	$ 5,330	$ 10,967

The increase for the year ended December 31, 2018 relates to a position taken in the current year. The increase for the year ended December 31, 2017 is related to tax positions taken during 2017 and prior years. If the $1 0 , 967 ,000 of unrecognized income tax benefit is recognized, approximately $1 0, 967 ,000 would impact the effective tax rate in the period in which each of the benefits is recognized.

The Company recognize s 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. The Company has not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2018 and 2017 . Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

NOTE 11: Related Party Transactions

On December 18, 2017, the Company entered into a consulting agreement for a term of up to five months with the Company's former Senior Vice President, Finance and Chief Accounting Officer. Pursuant to the terms of the consulting agreement through May 15, 2018, the consultant provided accounting and finance services related to the transition of financial leadership. The Company agreed to pay $150 per hour for such consulting services. The consultant also remained eligible for payout under the Company's 2017 Corporate Incentive Plan after he satisfactorily met certain performance obligations as outlined in the consulting agreement. During the year ended December 31 , 2018, the consultant was paid an aggregate of $53,925 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 28 , 2019

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

Date: March 28 , 2019

/s/ Robert Beechey
Robert Beechey
Chief Financial Officer (Principal Financial Officer and Principal 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 28 , 2019
/s/ Robert Beechey Robert Beechey	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 28, 2019
/s/ James T. LaFrance James T. LaFrance	Chairman of the Board of Directors	March 28, 2019
/s/ James S. Burns James S. Burns	Director	March 28, 2019
/s/ Veronica G. H. Jordan Veronica G. H. Jordan	Director	March 28, 2019
/s/ David Schreiber David Schreiber	Director	March 28, 2019
/s/ Nancy Cocozza Nancy Cocozza	Director	March 28, 2019

VERMILLION, INC.

AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN

Stock Option Award Agreement

You are hereby awarded this stock option (the " Option ") to purchase Shares of Vermillion, Inc. (the " Company "), subject to the terms and conditions set forth in this Stock Option Award Agreement (the " Award Agreement ") and in Amended and Restated Vermillion, Inc. 2010 Stock Incentive Plan (the " Plan "). A copy of the Plan is attached as **Exhibit A**. Terms below that begin with capital letters have the special meaning set forth in the Plan or in this Award Agreement.

This Award is conditioned on your execution of this Award Agreement within Thirty (30) days after the Grant Date specified in Section 1 below. By executing this Award Agreement, you will be irrevocably agreeing that all of your rights under this Award will be determined solely and exclusively by reference to the terms and conditions of the Plan, subject to the provisions set forth below. *As a result, you should not execute this Award Agreement until you have carefully considered the terms and conditions of the Plan and this Award, plus the information disclosed within the attached Plan prospectus, and consulted with your personal legal and tax advisors about all of these documents .*

1. Specific Terms. Your Option has the following terms:

Name of Participant	XX
Type of Option:	Incentive Stock Option (ISO) XX Shares Non-Incentive Stock Option (non-ISO)
Grant Date:	XX
Expiration Date:	The earlier of (i) 10 years after Grant Date, at 5:00 p.m. (E.D.T. or E.S.T., as applicable) on the Expiration Date, and (ii) thirty days after the termination of your Continuous Service.
Exercise Price:	U.S. $X.XX per Share.

Number of Shares subject to this Award:	XX
Dividend Equivalent Rights	Not applicable to this Award.
Vesting:	The portion of your Option that is an ISO will vest with respect to XX Shares on XX, and with respect to an additional XX Shares equally on each of the next XX anniversary dates thereafter. In all cases, vesting of your ISO or Non-Incentive Stock Option will only occur on a particular date if your Continuous Service has not ended before the particular vesting date (subject to the terms of any employment agreement between you and the Company).
Recapture and Recoupment	Section 14 of the Plan shall apply re Termination, Rescission, and Recapture of this Award. Section 15 shall apply re Recoupment of this Award.

2. **Manner of Exercise**. This Option shall be exercised in the manner set forth in the Plan, using the exercise form attached hereto as **Exhibit B**. The amount of Shares for which this Option may be exercised is cumulative; that is, if you fail to exercise this Option for all of the Shares vested under this Option during any period set forth above, then any Shares subject hereto that are not exercised during such period may be exercised during any subsequent period, until the expiration or termination of this Option pursuant to Sections 1 and 4 of this Award Agreement and the terms of the Plan. Fractional Shares may not be purchased.

3. **Special ISO Provisions**. If designated as an ISO, this Option shall be treated as an ISO to the extent allowable under Section 422 of the Code, and shall otherwise be treated as a Non-ISO. If you sell or otherwise dispose of Shares acquired upon the exercise of an ISO within 1 year from the date such Shares were acquired or 2 years from the Grant Date, you agree to deliver a written report to the Company within 10 days following the sale or other disposition of such Shares detailing the net proceeds of such sale or disposition.

4. **Termination of Continuous Service**. Subject to the terms of any employment agreement between you and the Company (and/or any Affiliate) that is in effect when your Continuous Service terminates, this Award shall be canceled and become automatically null and void immediately after termination of your Continuous Service for any reason, but only to the extent you have not become vested, pursuant to the terms of Section 1 above, on or before your Continuous Service ends.

5. **Designation of Beneficiary**. Notwithstanding anything to the contrary contained herein or in the Plan, following the execution of this Award Agreement, you may expressly designate a death beneficiary (the "Beneficiary") to your interest if any, in this Award and any underlying Shares. You shall designate the Beneficiary by completing and executing a designation of beneficiary agreement substantially in the form attached hereto as **Exhibit C** (the "Designation of Death Beneficiary") and delivering an executed copy of the Designation of Beneficiary to the Company. To the extent you do not duly designate a beneficiary who survives you, your estate will automatically be your beneficiary.

6. **Restrictions on Transfer of Award** . Your rights under this Award Agreement may not be sold, pledged, or otherwise transferred without the prior written consent of the Committee, except as hereinafter provided.

7. **Taxes** . Except to the extent otherwise specifically provided in an employment or consulting agreement between you and your employer, by signing this Award Agreement, you acknowledge that you shall be solely responsible for the satisfaction of any taxes that may arise pursuant to this Award (including taxes arising under Sections 409A (regarding deferred compensation) or 4999 (regarding golden parachute excise taxes), and that neither the Company nor the Administrator shall have any obligation whatsoever to pay such taxes or to otherwise indemnify or hold you harmless from any or all of such taxes. The Committee shall have the sole discretion to interpret the requirements of the Code, including Section 409A, for purposes of the Plan and this Award Agreement.

8. **Not a Contract of Employment** . By executing this Award, you acknowledge and agree that (i) any person who is terminated before full vesting of an award, such as the one granted to you by this Award Agreement, could claim that he or she was terminated to preclude vesting; (ii) you promise never to make such a claim; (iii) nothing in this Award Agreement or the Plan confers on you any right to continue an employment, service or consulting relationship with the Company, nor shall it affect in any way your right or the Company's right to terminate your employment, service, or consulting relationship at any time, with or without Cause; and (iv) the Company would not have granted this Award to you but for these acknowledgements and agreements.

9. **Investment Purposes** . By executing this Award Agreement, you represent and warrant that any Shares issued to you pursuant to your Option will be held for investment purposes only for your own account, and not with a view to, for resale in connection with, or with an intent in participating directly or indirectly in, any distribution of such Shares within the meaning of the Securities Act of 1933, as amended (the " Securities Act ").

10. **Securities Law Restrictions** . Regardless of whether the offering and sale of this Option or Shares under the Plan have been registered under the Securities Act, or have been registered or qualified under the securities laws of any state, the Company at its discretion may impose restrictions upon the sale, pledge or other transfer of such Shares (including the placement of appropriate legends on stock certificates or the imposition of stop-transfer instructions) if, in the judgment of the Company, such restrictions are necessary or desirable in order to achieve compliance with the Securities Act or the securities laws of any state or any other law or to enforce the intent of this Award.

11. **Headings** . Section and other headings contained in this Award Agreement are for reference purposes only and are not intended to describe, interpret, define, or limit the scope or intent of this Award Agreement or any provision hereof.

12. **Severability** . Every provision of this Award Agreement and of the Plan is intended to be severable. If any term hereof is illegal or invalid for any reason, such illegality or invalidity shall not affect the validity or legality of the remaining terms of this Award Agreement.

13. **Counterparts** . This Award Agreement may be executed by the parties hereto in separate counterparts, each of which when so executed and delivered shall be an original, but all such counterparts shall together constitute one and the same instrument.

14. **Notices** . Any notice or communication required or permitted by any provision of this Award Agreement to be given to you shall be in writing and shall be delivered electronically, personally, or sent by certified mail, return receipt requested, addressed to you at the last address that the Company

had for you on its records. Each party may, from time to time, by notice to the other party hereto, specify a new address for delivery of notices relating to this Award Agreement. Any such notice shall be deemed to be given as of the date such notice is personally or electronically delivered or properly mailed.

15. **Binding Effect**. Except as otherwise provided in this Award Agreement or in the Plan, every covenant, term, and provision of this Award Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, legatees, legal representatives, successors, transferees, and assigns.

16. **Modifications**. This Award Agreement may be modified or amended at any time, in accordance with Section 18 of the Plan.

17. **Plan Governs**. By signing this Award Agreement, you acknowledge that you have received a copy of the Plan and that your Award Agreement is subject to all the provisions contained in the Plan, the provisions of which are made a part of this Award Agreement and your Award is subject to all interpretations, amendments, rules and regulations which from time to time may be promulgated and adopted pursuant to the Plan. In the event of a conflict between the provisions of this Award Agreement and those of the Plan, the provisions of the Plan shall control.

18. **Governing Law**. The laws of the State of California shall govern the validity of this Award Agreement, the construction of its terms, and the interpretation of the rights and duties of the parties hereto.

BY YOUR SIGNATURE BELOW, along with the signature of the Company's representative, you and the Company agree that this Award is made under and governed by the terms and conditions of this Award Agreement and the Plan.

VERMILLION, INC.

By:
Name:
Title:

PARTICIPANT

The undersigned Participant hereby accepts the terms of this Award Agreement and the Plan.

By:

Name of Participant:

VERMILLION, INC.
AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN

Plan Document

Intentionally omitted

Exhibit B

VERMILLION, INC.
AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN

Form of Exercise of Stock Option Award Agreement

Vermillion, Inc.

[Company Address]

Attention: _____
Dear Sir or Madam:

The undersigned elects to exercise his/her Option to purchase _____ shares of Common Stock of Vermillion, Inc. (the " Company ") under and pursuant to a Stock Option Agreement dated as of _____.

1. Delivered herewith is a certified or bank cashier's or teller's check and/or shares of Common Stock owned by the undersigned, valued at the closing sale price of the stock on the business day prior to the date of exercise, as follows:

$_____ in cash or check
$_____ in the form of ____ shares of Common Stock,
valued at $_____ per share
$ _____ **Total**

2. The undersigned elects a net exercise, hereby authorizing the Company to withhold from the shares otherwise subject to this Option a number of shares sufficient to cover the exercise price and minimum statutory withholding taxes payable pursuant to this exercise.

If method 1 is chosen, the name or names to be on the stock certificate or certificates and the address and Social Security Number of such person(s) is as follows:

Name:

Address:

Social Security Number

Very truly yours,

_____
Date Optionee

*The Committee must approve this method in writing before your election

Exhibit C

VERMILLION, INC.
AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN

Designation of Death Beneficiary

In connection with the Awards designated below that I have received pursuant to the Amended and Restated Vermillion, Inc. 2010 Stock Incentive Plan (the " Plan "), I hereby designate the person specified below as the beneficiary upon my death of my interest in such Awards. This designation shall remain in effect until revoked in writing by me.

Name of Beneficiary:

Address: _____

Social Security No.:

This beneficiary designation relates to any and all of my rights under the following Award or Awards:

any Award that I have received or ever receive under the Plan.

the _____ Award that I received pursuant to an award agreement dated _____ __, ____ between myself and the Company.

I understand that this designation operates to entitle the above named beneficiary, in the event of my death, to any and all of my rights under the Award(s) designated above from the date this form is delivered to the Company until such date as this designation is revoked in writing by me, including by delivery to the Company of a written designation of beneficiary executed by me on a later date.

Date:

By:

Name of Participant:

VERMILLION, INC.

2010 STOCK INCENTIVE PLAN

Restricted Stock Unit Award Agreement

You are hereby awarded Restricted Share Units (the " RSUs ") subject to the terms and conditions set forth in this Restricted Share Unit Award Agreement (the " Award Agreement " or " Award "), and in the Vermillion, Inc. 2010 Stock Incentive Plan (the " Plan "). A copy of the Plan is attached as **Exhibit A** . Terms beginning with initial capital letters within this Agreement have the special meaning defined in the Plan (or in this Award Agreement, if defined herein).

This Award is conditioned on your execution of this Award Agreement within 45 (forty-five) days after the Grant Date specified in Section 1 below. By executing this Award Agreement, you will be irrevocably agreeing that all of your rights under this Award will be determined solely and exclusively by reference to the terms and conditions of the Plan, subject to the provisions set forth below. *As a result, you should not execute this Award Agreement until you have carefully considered the terms and conditions of the Plan and this Award, plus the information disclosed within the attached Plan prospectus, and consulted with your personal legal and tax advisors about all of these documents.*

1. Specific Terms . Your RSUs have the following terms:

Name of Participant	XX
Number of RSUs Subject to Award	XX
Purchase Price per Share (if applicable)	Not applicable.
Grant Date	XX
Vesting	Your Award will vest at the rate of X on each XX anniversary date beginning XX, provided that your Continuous Service has not ended before the particular vesting date (subject to any employment agreement between you and the Company).
Deferral Elections	☐ Allowed in accordance with Section 8(f) and 9 of the Plan ☑ Not allowed.

Recapture and Recoupment	☑ Section 14 of the Plan shall apply re Termination, Rescission, and Recapture of this Award. ☐ Section 15 shall apply re Recoupment of this Award.

2. **Termination of Continuous Service**. Subject to the terms of any employment agreement between you and the Company (and/or any Affiliate) that is in effect when your Continuous Service terminates, this Award shall be canceled and become automatically null and void immediately after termination of your Continuous Service for any reason, but only to the extent you have not become vested, pursuant to terms of Section 1 above, on or before the date that your Continuous Service ends.

3. **Satisfaction of Vesting Restrictions**. No Shares will be issued before you complete the requirements that are necessary for you to vest in the Shares underlying your RSUs. As soon as practicable after the later of (i) the date on which your RSUs vest in whole or in part, or (ii) the distribution date or dates set forth in your deferral and distribution election forms (if allowed under Section 1 and made by you), the Company will issue to you or your duly-authorized transferee, free from vesting restrictions (but subject to such legends as the Company determines to be appropriate), one Share for each vested RSU with such number of Shares issued to you being reduced by a number of Shares having a fair market value equal to the minimum statutory tax withholding required in connection with the vesting of your RSUs, and with cash being withheld from your pay for any additional withholding and employment taxes that applicable tax laws may require. In the event the Company cannot (under applicable legal, regulatory, listing or other requirements, or otherwise) satisfy such tax withholding obligation in such method, the Company may satisfy such withholding by: (i) requiring you to pay such amount in cash or check; or (ii) by deducting such amount out of any other compensation otherwise payable to you. Certificates shall not be delivered to you unless all applicable employment and tax-withholding obligations have been satisfied.

4. **Dividends**. You shall have Dividend Equivalent Rights with respect to this Award, and Section 10 of the Plan shall accordingly determine your right to collect any cash dividends or Share dividends that are declared and paid to the holders of Shares between the Grant Date and each vesting or deferred settlement date upon which you are entitled to receive Shares to settle this Award. To the extent that your Continuous Service ends before full vesting of the RSUs subject to this Award, you will forfeit all cash and Share-based dividends that are attributable to all of your non-vested RSUs.

5. **Designation of Beneficiary**. Notwithstanding anything to the contrary contained herein or in the Plan, following the execution of this Award Agreement, you may expressly designate a death beneficiary (the "Beneficiary") to your interest, if any, in this Award and any underlying Shares. You shall designate the Beneficiary by completing and executing a designation of beneficiary agreement substantially in the form attached hereto as **Exhibit B** (the "Designation of Death Beneficiary") and delivering an executed copy of the Designation of Beneficiary to the Company. To the extent you do not duly designate a beneficiary who survives you, your estate will automatically be your beneficiary.

6. **Restrictions on Transfer of Award**. Your rights under this Award Agreement may not be sold, pledged, or otherwise transferred without the prior written consent of the Committee.

7. **Taxes**. Except to the extent otherwise specifically provided in an employment agreement between you and the Manager, by signing this Award Agreement, you acknowledge that you shall be solely responsible for the satisfaction of any applicable taxes that may arise pursuant to this Award (including taxes arising under Code Section 409A (regarding deferred compensation) or 4999 (regarding golden parachute excise taxes), and that neither the Company nor the Administrator shall have any obligation whatsoever to pay such taxes or to otherwise indemnify or hold you harmless from any or all of such taxes. The Committee shall have the sole discretion to interpret the requirements of the Code, including Section 409A, for purposes of the Plan and this Award Agreement.

8. **Not a Contract of Employment**. By executing this Award Agreement you acknowledge and agree that (i) nothing in this Award Agreement or the Plan confers on you any right to continue an employment, service or consulting relationship with the Company, nor shall it affect in any way your right or the Company's right to terminate your employment, service, or consulting relationship at any time, with or without Cause; and (ii) the Company would not have granted this Award to you but for these acknowledgements and agreements.

9. **Long-term Consideration for Award**. If Section 1 above provides for the application of Plan Section 14 to this Award, then by executing this Award Agreement you acknowledge and agree that the Company's key consideration in granting this Award is securing your long-term commitment to serve as a key employee who will advance and promote the Company's business interests and objectives, and, accordingly, you agree that this Award shall be subject to the terms and conditions of Plan Section 14 (relating to the termination, rescission, and recapture of this Award if you violate certain commitments made therein to the Company) as material and indivisible consideration for this Award.

10. **Investment Purposes**. By executing this Award, you represent and warrant to the Company that any Shares issued to you pursuant to your RSUs will be for investment for your own account and not with a view to, for resale in connection with, or with an intent of participating directly or indirectly in, any distribution of such Shares within the meaning of the Securities Act of 1933, as amended (the "Securities Act").

11. **Securities Law Restrictions**. Regardless of whether the offering and sale of Shares under the Plan have been registered under the Securities Act, or have been registered or qualified under the securities laws of any state, the Company at its discretion may impose restrictions upon the sale, pledge or other transfer of such Shares (including the placement of appropriate legends on stock certificates or the imposition of stop-transfer instructions) if, in the judgment of the Company, such restrictions are necessary or desirable in order to achieve compliance with the Securities Act or the securities laws of any state or any other law or to enforce the intent of this Award.

12. **Headings**. Section and other headings contained in this Award Agreement are for reference purposes only and are not intended to describe, interpret, define or limit the scope or intent of this Award Agreement or any provision hereof.

13. **Severability**. Every provision of this Award Agreement and of the Plan is intended to be severable. If any term hereof is illegal or invalid for any reason, such illegality or invalidity shall not affect the validity or legality of the remaining terms of this Award Agreement.

14. **Counterparts**. This Award Agreement may be executed by the parties hereto in separate counterparts, each of which when so executed and delivered shall be an original, but all such counterparts shall together constitute one and the same instrument.

15. **Notices**. Any notice or communication required or permitted by any provision of this Award Agreement to be given to you shall be in writing and shall be delivered electronically, personally, or sent by mail, addressed to you at the last address that the Company had for you on its records. Each party may, from time to time, by notice to the other party hereto, specify a new address for delivery of notices relating to this Award Agreement. Any such notice shall be deemed to be given as of the date such notice is personally or electronically delivered or properly mailed.

16. **Binding Effect**. Except as otherwise provided in this Award Agreement or in the Plan, every covenant, term, and provision of this Award Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, legatees, legal representatives, successors, transferees, and assigns.

17. **Modifications**. This Award Agreement may be modified or amended at any time in accordance with Section 18 of the Plan.

18. **Plan Governs**. By signing this Award Agreement, you acknowledge that you have received a copy of the Plan and that your Award Agreement is subject to all the provisions contained in the Plan, the provisions of which are made a part of this Award Agreement, and your Award is subject to all interpretations, amendments, rules and regulations which from time to time may be promulgated and adopted pursuant to the Plan. In the event of a conflict between the provisions of this Award Agreement and those of the Plan, the provisions of the Plan shall control.

19. **Governing Law**. The laws of the State of California shall govern the validity of this Award Agreement, the construction of its terms, and the interpretation of the rights and duties of the parties hereto.

BY YOUR SIGNATURE BELOW, along with the signature of the Company's representative, you and the Company agree that this Award is made under and governed by the terms and conditions of this Award Agreement and the Plan.

Vermillion, Inc.

By:
Name:
Title:

PARTICIPANT

The undersigned Participant hereby accepts the terms of this Award Agreement and the Plan.

By:
Name of Participant:

Exhibit A

Vermillion, Inc.
2010 Stock Incentive Plan

Plan Document

Intentionally omitted

Vermillion, Inc.
2010 Stock Incentive Plan

Designation of Death Beneficiary

In connection with the Awards designated below that I have received pursuant to the Plan, I hereby designate the person specified below as the beneficiary upon my death of my interest in such Awards. This designation shall remain in effect until revoked in writing by me.

Name of Beneficiary:

Address:

Social Security No.:

This beneficiary designation relates to any and all of my rights under the following Award or Awards:

any Award that I have received or ever receive under the Plan.

the _____ Award that I received pursuant to an award agreement dated _____ __, ____ between myself and the Company.

I understand that this designation operates to entitle the above named beneficiary, in the event of my death, to any and all of my rights under the Award(s) designated above from the date this form is delivered to the Company until such date as this designation is revoked in writing by me, including by delivery to the Company of a written designation of beneficiary executed by me on a later date.

Date:

By:
Name of Participant

Sworn to before me this
____day of _____, 20__
_____
Notary Public
County of _____
State of _____

Exhibit 21.0

Vermillion, Inc. Subsidiaries

December 31, 2018

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Vermillion, Inc.
Austin, Texas

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-106434, 333-109556, 333-139416, 333-189929, 333-202032, 333-217249 and 333-221092) and Form S-8 (Nos. 333-167204, 333-193312, 333-205855 and 333-226462) of Vermillion, Inc. of our report dated March 28, 2019, relating to the consolidated financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Austin, Texas
March 28, 2019

Exhibit 31.1

CERTIFICATION

I, Valerie B. Palmieri, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2018 of Vermillion, Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 28 , 201 9

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

EXHIBIT 31.2

CERTIFICATION

I, Robert Beechey , certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2018 of Vermillion, Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 28 , 201 9

/s/ Robert Beechey
Robert Beechey
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.0

Certifica tion

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

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

with Respect to the Annual Report on Form 10-K

for the Year Ended December 31, 2018

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

1. The Company's annual report on Form 10-K for the year ended December 31, 2018 , (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and
2. The i nformation contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28 , 2019 /s/ Valerie B. Palmieri

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

Date: March 28 , 2019 /s/ Robert Beechey

Robert Beechey
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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