ASPIRA WOMEN'S HEALTH INC.

FORM 10-K
(Annual Report)

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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2019 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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**VRML**	**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 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 $47,231,865 and is based upon the last sales price as quoted on The NASDAQ Capital Market as of June 28, 2019.

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 24, 2020, the registrant had 97,288,657 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, 2019.

VERMILLION, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2019

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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;
- our plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders;
- our planned business strategy and the anticipated timing of the implementation thereof;
- plans with respect to our market expansion and growth, including plans to market OVA1, Overa, OVA1PLUS and ASPiRA GenetiX outside the United States;
- plans to develop new algorithms and molecular diagnostic tests;
- plans to develop a product or tool combining OVA1PLUS with results of a symptom index;
- plans regarding our ability to develop a product to assess the risk of gynecologic diseases that are difficult to detect through OVAinherit screening;
- plans to establish payer coverage for Overa and ASPiRA GenetiX separately 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;
- our planned focus on the execution of five core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to address unmet medical needs for women faced with gynecologic disease and other conditions and the continued development of our business;
- expectations 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");
- plans to expand our product offerings to additional pelvic disease conditions, including endometriosis;
- plans to develop an ethnicity-specific pelvic mass risk assessment:
- plans to commercialize Overa and ASPiRA GenetiX, our offering to detect hereditary breast and ovarian cancer syndrome and carriers of the gene;
- plans to develop informatics products and develop and perform laboratory developed tests ("LDTs");
- plans with respect to the Company's pelvic mass registry;
- our ability to improve sensitivity and specificity over traditional diagnostic biomarkers;
- expectations regarding existing and future collaborations and partnerships, including OVA1, Overa, OVA1PLUS and ASPiRA GenetiX distribution and technology transfer 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, Overa, OVA1PLUS and ASPiRA GenetiX 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, Overa, OVA1PLUS and ASPiRA GenetiX in 2020;
- expectations regarding the results of our clinical utility studies;
- our ability to use our net operating loss carryforwards;
- anticipated future tax liability under U.S. federal and state income tax legislation;
- expected market adoption of our diagnostic tests, including OVA1, Overa, OVA1PLUS and ASPiRA GenetiX;
- expectations regarding our ability to launch new products we develop, license, co-market or acquire;
- expectations regarding the size of the markets for our products;
- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations;
- 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;
- expectations regarding our first diagnostic algorithm LDT, OVAnex, formerly referred to as Diagnostic Algorithm #1 and Watch and Wait, and studies relating thereto; and
- expectations regarding our second diagnostic algorithm LDT, Endocheck, formerly referred to as Diagnostic Algorithm #2, and studies relating thereto.

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, Overa, OVA1PLUS or ASPiRA GenetiX 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, Overa, OVA1PLUS and ASPiRA GenetiX 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; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; our ability to use our net operating loss carryforwards; the liquidity and trading volume of our common stock; and the concentration of ownership of our common stock.

ITEM 1. BUSINESS

Company Overview

Corporate Vision: To transform the state of women's health, globally, starting with ovarian cancer. We aim to ensure that women of all ages, stages and ethnicities have the best solutions available to assess their personalized risk of cancer at the earliest stage when it matters most. Our end goal is to serve a large global pelvic mass population and overall women's health sector with a platform coupled with proprietary science and data tools which will drive better health and wellbeing for each patient we serve.

Our plan is to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders. We plan to continue commercializing our new generation of technology and decentralized technology transfer service platform. We also intend to raise public awareness regarding the diagnostic superiority of OVA1 as compared to cancer antigen 125 ("CA125") for African American women with adnexal masses.

In the fourth quarter of 2018, we launched our new generation of technology, OVA1PLUS. OVA1PLUS is designed to improve accuracy and reduce false positive diagnoses by over 30% by leveraging the strengths of OVA1's sensitivity and Overa's specificity. OVA1PLUS will also be available through a decentralized platform structure enabling hospital networks and super groups to run the test in their labs.

We expanded our commercial strategy in late 2018 and the first quarter of 2019 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 of diagnostic algorithms that will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value. The first diagnostic algorithm LDT, which we refer to internally as OVAnex, and formerly referred to as Diagnostic Algorithm #1 and Watch and Wait, focuses on monitoring women with pelvic masses. We expect OVAnex to be available for commercial use in 2021. The second diagnostic algorithm LDT, Endocheck, formerly known as Diagnostic Algorithm #2, will focus on endometriosis. We also plan to expand our portfolio of products to include OVAinherit, which is the basis for a high-risk screening test for those patients who are genetically predisposed to ovarian cancer. This algorithm will include genetics, proteins and other modalities to assess the risk. All of our products are focused on gynecologic diseases that cannot be assessed through a traditional biopsy.

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 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 patients. 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.

Science of Biomarkers: 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 pre-market notification clearance under the Federal Food, Drug and Cosmetic Act, known as 510(k) clearance, of OVA1 as an IVD software device.

Our Business and Products: We currently market and sell the following products and related services: (1) OVA1, 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; (2) Overa, a second-generation biomarker panel intended to maintain our product's high sensitivity while improving specificity; (3) OVA1PLUS, a service offering combining our OVA1 and Overa products, designed to improve accuracy and reduce false elevations in the intermediate risk area by over 30% by leveraging the strengths of OVA1's (MIA) sensitivity and Overa's (MIA2G) specificity; and (4) ASPiRA GenetiX, a genetic test for specific women's health diseases, initially focused on detecting hereditary breast and ovarian cancer syndrome ("HBOC") and Carrier screening, genetic screening for carriers of disease. OVA1 received FDA clearance in September 2009, and Overa received FDA clearance in March 2016. OVA1 and Overa each use the Roche cobas 4000, 6000 and 8000 platforms and OVA1, Overa and OVA1PLUS are each available through our decentralized platform and cloud service testing. Through December 31, 2019, Vermillion's product and related services revenue has primarily been limited to revenue generated by sales of OVA1, with ASPiRA GenetiX revenue beginning in the fourth quarter of 2019.

We are currently developing three additional products and related services, including two diagnostic algorithms as part of an LDT product series, OVAnex and Endocheck, respectively, as well as a high-risk screening algorithm, OVAinherit, for patients who are genetically predisposed to ovarian cancer.

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

In the fourth quarter of 2018, we entered into a comprehensive study agreement with Clalit Health Services to validate OVA1 (MIA), OVERA® (MIA2G) and OVA1PLUS on the Israeli population. Vermillion's technology will be studied on this high risk hereditary ovarian cancer 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.

In the fourth quarter of 2019, we completed all outstanding service revenue contract commitments relating to our ASPiRA IVD subsidiary. The Company is no longer pursuing IVD contracts and has fulfilled all contractual obligations under previous contracts. All direct employees and contract labor have been terminated.

About OVA1 and Overa: 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 November 2016, the American College of Obstetricians and Gynecology ("ACOG") issued Practice Bulletin Number 174, which included OVA1 as a "Multivariate Index Assay", outlining ACOG's clinical management guidelines for adnexal mass management. Practice Bulletin Number 174 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 achieved parity with CA125 as a Level B clinical recommendation for the management of adnexal masses.

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. Practice Bulletins are also the only clinical management tool used for adnexal masses. Although there are Practice Bulletins, guidelines do not exist for adnexal masses. ACOG guidelines do exist, however, for ovarian cancer management.

About OVA1PLUS: In the fourth quarter of 2018, we launched OVA1PLUS. OVA1PLUS helps drive earlier detection, which in turn lowers overall healthcare costs and reduces inefficiencies in the care pathway. OVA1PLUS is available through a decentralized platform structure, which allows other facilities, including hospital networks and large doctor practices, also known as super groups, to perform OVA1PLUS locally and upload raw data to us and receive the OVA1PLUS score, enabling increased reach and access in the geographic areas we serve. We plan to eventually pursue larger-scale partnerships to leverage this decentralized platform.

About Decentralized Technology Transfer: In the fourth quarter of 2018, we launched our new platform and cloud service for OVA1 and Overa testing. The platform and web service allow third-party facilities to perform OVA1 and Overa and calculate OVA1 and Overa scores locally, enabling increased reach and access in the markets we serve.

About ASPiRA GenetiX: In June 2019, we launched ASPiRA GenetiX, which is genetic testing for specific women's health diseases, with a core focus on ovarian cancer. ASPiRA GenetiX's initial offering is designed to detect hereditary breast and ovarian cancer syndrome ("HBOC") and Carrier screening, genetic screening for carriers of disease. Women who test positive for HBOC variants have a significantly elevated risk of developing ovarian cancer. ASPiRA GenetiX complements OVA1PLUS and is sold at the same call point as OVA1PLUS. In time, ASPiRA GenetiX testing results could be reported in a combined report with OVA1PLUS. The testing is performed by Fulgent Genetics, Inc.

About OVAnex: We are developing an LDT product series of diagnostic algorithms that will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value. The first diagnostic algorithm LDT, which we refer to internally as OVAnex, and formerly referred to as Diagnostic Algorithm #1 and Watch and Wait, focuses on monitoring women with pelvic masses. The new test will have a strong sensitivity and specificity as well as a strong negative predictive value of greater than 99%, which will allow physicians to serially monitor women with a mass to delay or avoid unnecessary surgery. Tackling serial monitoring, which involves testing each patient two to four times a year, presents a new and potentially large market opportunity for us. The test will be initially launched as a serial monitoring LDT only, but the 2020 prospective monitoring study will be designed to enable us to submit for FDA clearance if we choose to do so. We expect OVAnex to be commercially available in 2021.

About Endocheck: The second LDT product we are developing is known as Endocheck, formerly referred to as Diagnostic Algorithm #2, will focus on endometriosis. The Endocheck test is being developed to act as an aide in detection of endometriosis. We expect to develop and validate the test in 2021 and commercially launch in the fourth quarter of 2022.

About OVAinherit: We also plan to expand our portfolio of products to include OVAinherit, which is the basis for a high-risk screening test for those patients which are genetically predisposed. This algorithm will include genetics, proteins and other modalities to assess the risk of ovarian cancer.

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

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

- Expanding the distribution platform beyond the U.S. by launching Overa, a next generation biomarker panel and OVA1 on the same platform, 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;

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

- Expanding our product offerings to additional pelvic disease conditions such as benign mass monitoring and endometriosis 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; and

- Coupling our OVA1 products with an individual's hereditary risk to refine ovarian cancer risk assessment.

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.

Studies and Publications

Below is a list of peer reviewed publications or articles published by outside parties to date regarding our technology, including five new publications in 2019.

#	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.
14	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.
15	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.
16	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.
17	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.
18	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.

19	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.
20	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.
21	Clinical performance comparison of two IVDMIA's for pre-surgical assessment of ovarian cancer risk	Shulman, et. al. Advances in Therapy 2019	2019	N=993	ROMA misclassified 51/245 malignancies (including 10 high-grade ovarian malignancies) whereas MIA2G misclassified 22/245 (including 5 high-grade ovarian malignancies). In early-stage cancer, ROMA misclassified more often than MIA2G (20 vs. 8).
22	Performance of a Second-Generation Multivariate Index Assay and Ovarian Imaging in the Malignancy Assessment of Adnexal Masses	Fredericks et al. Journal of Surgical Oncology	2019	N=878	For evaluating ovarian tumors, combining imaging with a second-generation multivariate index assay results in higher sensitivity and negative predictive value over imaging alone.
23	Ethnic Disparity in Clinical Performance Between Multivariate Index Assay and CA125 in Detection of Ovarian Malignancy	Dunton, et al. Journal, Future Oncology	2019	N=274	Clinical performance of OVA1 was better than CA125 in African American women.
24	Ethnicity and tumor markers in ovarian neoplasms	Dunton, et al. Biomarkers in Cancer	2019	N=274	Clinical performance of OVA1 was better than ROMA in African American women.
25	Adnexal Mass Risk Assessment – A Multivariate Index Assay for Malignancy Risk Stratification	Zhang et al. Journal, Future Oncology	2019	N=2092	Initial OVA3/AMRA validation. AMRA is a multivariate serum test developed to assess the risk of a mass with indeterminate features, intended to separate out the relatively small number of malignancies from the benign masses for which a nonsurgical approach may be taken.

The Diagnostic Field

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 December 2018, Allied Market Research, a market research and business consulting partnership, published a study which forecasts the global IVD market to reach $93.6 billion by 2025, growing at a compound annual growth rate of 4.8% from 2018 to 2025. 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.

Ovarian Cancer

Background

Commonly known as the "silent killer," ovarian cancer leads to nearly 14,000 deaths each year in the United States. As of early 2020, The American Cancer Society ("ACS") estimated that nearly 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 National Cancer Institute, when ovarian cancer is diagnosed at its earliest stage, patients have up to a 92.4% 5-year survival rate following surgery and/or chemotherapy if detected in stage 1. However, many ovarian cancer patients are diagnosed after 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 24.3%.

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 Society of Gynecologic Oncology ("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.

In November 2016, ACOG practice bulletin 174 (November 2016) states the following "The multivariate index assay has demonstrated higher sensitivity and negative predictive value for ovarian malignancy when compared with clinical impression and CA 125 alone."[3]

The ovarian cancer information page on American Cancer Society's website (cancer.org/cancer/ovarian-cancer/about/new-research.html) indicates that:

> For women who have an ovarian tumor, a test called OVA1 can measure the levels of 5 proteins in the blood. The levels of these proteins, when looked at together, are used to determine whether a woman's tumor should be considered low risk or high risk. If the tumor is labeled 'low risk' based on this test, the woman is not likely to have cancer. If the tumor is considered 'high risk,' the woman is more likely to have a cancer, and should see a specialist (a gynecologic oncologist). This test is NOT a screening test and it is NOT a test to decide if you should have surgery or not− it is meant for women who have an ovarian tumor where surgery has been decided but have not yet been referred to a gynecologic oncologist. [4]

In 2019, two studies were released indicating superior clinical performance of OVA1 over CA125 and OVA1 over CA125, HE4 and Risk of Malignancy Algorithm ("ROMA") in African American women. [5],[6]

[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.

[3] The American College of Obstetrics and Gynecologists Practice Bulletin No. 174: Evaluation and Management of Adnexal Masses. Obstet & Gynecol. 2016 Nov; 128(5):e210-e226.

[4] The American Cancer Society medical and editorial content team. "What's New in Ovarian Cancer Research?" *About Ovarian Cancer Ovarian*, American Cancer Society, 11 Apr. 2018.

[5] Dunton C, Bullock RG, Fritsche H. Ethnic Disparity in Clinical Performance Between Multivariate Index Assay and CA125 in Detection of Ovarian Malignancy. Future Oncology. 2019 Aug.

[6] Dunton C, Bullock RG, Fritsche H. Multivariate Index Assay is Superior to CA125 and HE4 Testing in Detection of Ovarian Malignancy in African-American Women. Biomark Cancer. 2019 Jun.

Commercialization and Distribution

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-owned subsidiary, ASPiRA LABS. Pursuant to this agreement as amended as of March 11, 2020, 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 any tests that Quest Diagnostics offers.

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 agreement regarding decentralized technology transfer for Overa specimen testing.

We ultimately plan to commercialize OVA1, Overa, OVA1PLUS and ASPiRA GenetiX on a global level. We currently hold CE marks for OVA1 and Overa. In addition, each of OVA1 and Overa are already offered on our global testing platform, which allows both tests to be deployed worldwide.

Customers

In the United States, our clinical customer base can be segmented into three major groups: physicians, physician office laboratories and hospital laboratories. Both within and outside the United States, laboratories may become our customers, either directly with us through payer contracts or client bill arrangements or via decentralized technology transfer 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.

In 2019, two studies identified a disparity in diagnosis for African American women and demonstrated that OVA1 has superior sensitivity for detection in this population over CA125 or ROMA.

Some of the new biomarkers currently under consideration for validation are (a) 15 serum proteins highly associated with ovarian cancer that were identified by mass spectrometry; (b) circulating methylated DNA fragments from cancer genes; and (c) micro-RNA profiles in serum.

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. We currently hold CE marks for OVA1 and Overa. We are targeting markets outside of the United States now that we have Overa cleared on the Roche cobas platform, which is available globally. We currently have two decentralized technology transfer contracts with distributors outside the United States.

Approximately 12,898 OVA1 tests were performed in 2019 compared to 7,679 in 2018, with the increase being attributed to expanded commercial efforts. In 2019, we continued to increase sales through experienced Market Development Managers and Regional Account Managers. As awareness of our product 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, Overa and OVA1PLUS.

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 our products. We have instituted a "Patient Transparency Program" to assist with this process by proactively assessing insurance and educating patients on testing costs prior to testing being performed.

Revenue and 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. Through December 31, 2019, Vermillion's product and related services revenue has primarily been limited to revenue generated by sales of OVA1, with ASPiRA GenetiX beginning to generate revenue in the fourth quarter of 2019.

In the fourth quarter of 2019, we completed all outstanding service revenue contract commitments relating to our ASPiRA IVD subsidiary.

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. This rate is extended through 2021.

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. This rate is extended through 2021.

In January 2019, we announced that Cigna added OVA1®(MIA) to its national preferred coverage list.

In June 2019, we announced that both BlueCross BlueShield of Texas and BlueCross BlueShield of Arizona began offering preferred coverage for OVA1®(MIA).

We are reimbursed for ASPiRA GenetiX based on either contracted rates or out of network rates for covered testing under patient insurance plans.

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 studies done in 2013 and 2019, 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.

We also compete in the development and commercialization of genetic testing for hereditary cancer and carrier screening for autosomal-recessive or X-linked conditions with companies in the United States and internationally. The testing services offered by competitive clinical laboratories, if performed in-house, may be easier to develop and market than our testing, which is performed by a third party.

Several companies such as Invitae Corporation, Myriad Genetics, Inc., Laboratory Corporation of America, Inc., Natera, Ambry Genetics, and Progenity, Inc. offer similar genetic testing for carrier screening and hereditary genetic testing. We believe that the technology offered by our testing is competitive with these companies and that our existing relationships with gynecologist offices enhance our ability to reach customers.

Intellectual Property Protection

Our intellectual property includes the federally registered trademarks for *Vermillion, OVA1 Overa* and *OVA1PLUS* as well as a pending trademark for *ASPiRA GenetiX* 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 18 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 23 patent families and are directed to diagnostic technologies.

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. OVA1PLUS is a service offering that combines OVA1 and Overa. Our principal supplier is Roche Diagnostics Corporation.

Environmental Matters

Medical Waste

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

Occupational Safety

In addition to its comprehensive regulation of safety in the workplace, the Federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to chemicals and transmission of the blood-borne and airborne pathogens. Although we believe that we have complied in all

material respects with such federal, state and local laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

Specimen Transportation

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

Government Regulation

General. Our activities related to diagnostic products are, or have the potential to be, subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of our products. The Federal Food, Drug and Cosmetic Act requires that medical devices introduced to the United States market, unless exempted by regulation, be the subject of either a pre-market notification clearance, known as a 510(k) clearance or 510(k) *de novo* clearance, or a pre-market approval ("PMA"). OVA1 was cleared by the FDA in September 2009 under the 510(k) *de novo* guidelines. OVA1 was the first FDA-cleared blood test for the pre-operative assessment of ovarian masses. We 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, 2019, we had 52 full-time employees and 53 total 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 $422 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 2020. 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, 2019 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 2020. 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 2017, 2018 and 2019 was 8,575, 7,679 and 12,898, 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, Overa, OVA1PLUS, or ASPiRA GenetiX 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, Overa, OVA1PLUS and ASPiRA GenetiX 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, Overa, OVA1PLUS and ASPiRA GenetiX are largely out of our control. We have experienced volatility in the coverage and reimbursement of OVA1 and Overa 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 and Overa. 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, Overa, OVA1PLUS or ASPiRA GenetiX or if third-party payers change their coverage or reimbursement policies with respect to OVA1, Overa, OVA1PLUS or ASPiRA GenetiX, 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 August 2, 2019, 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 30, 2020, Vermillion was granted an additional 180-calendar day compliance period, or until July 27, 2020, to regain compliance with the minimum bid price requirement. There is no assurance that we will be able to regain compliance by the July 27, 2020 extended deadline, and there is no assurance that we will otherwise 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 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. Also, outcomes of prospective and retrospective trials, for OVAnex which are essential for clinical validation, are uncertain. In addition, our efforts to develop other diagnostic tests, such as Endocheck, 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, Overa, OVA1PLUS and/or ASPiRA GenetiX 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, OVA1PLUS and ASPiRA GenetiX and developing 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, Overa or OVA1PLUS 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, Overa and OVA1PLUS provide significant improvement over current clinical practices, our ability to commercialize OVA1, Overa and OVA1PLUS 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 successful. In addition, competitors, such as Becton Dickinson, ArrayIt Corporation, Abbott Laboratories and others 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, Overa and OVA1PLUS at a point that recognizes the value-added by its increased sensitivity for detecting ovarian malignancy. If others develop a test that is viewed to be similar to OVA1, Overa or OVA1PLUS in efficacy but is priced at a lower point, we and/or our strategic partners may have to lower the price of OVA1, Overa or OVA1PLUS 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 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.

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.

Failure to comply with FDA requirements for post-market monitoring of our products may affect the commercialization of our products, therefore adversely affecting our business. 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's post-market surveillance requirement is completed but still in the final steps for closure 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.

Additionally, 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 OVA1and Overa (or OVA1PLUS, which is a reflex testing service in which both OVA1 and Overa are used), we use those components in compliance with QSR. Any failure to do so would have an adverse effect on our ability to commercialize OVA1, Overa or OVA1PLUS. Our suppliers' manufacturing facilities, since they manufacture finished kits that we use in OVA1, Overa and OVA1PLUS, 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, Overa and OVA1PLUS 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, Overa or OVA1PLUS 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, Overa or OVA1PLUS 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.

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 2018 and 2019, virtually all of our product revenue was generated in the United States. If we are able to successfully commercialize our products outside the United States, there are risks inherent in conducting business internationally, including the following:

- data privacy laws that may apply to the transmission of any clients' and employees' data to the United States;
- import/export sanctions and restrictions;
- compliance with applicable anti-corruption laws;
- difficulties in managing international distributors;
- accounting, tax and legal complexities arising from international operations;
- potential difficulties in transferring funds generated overseas to the United States in a tax efficient manner; and
- political and economic instability, including recent recessionary trends.

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, epidemics or pandemics such as COVID-19, and other 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 adversely impact sales of and reimbursement for our tests, which would have an adverse effect on our business, financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA") 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. Other changes to healthcare laws may adversely affect our business, financial condition and results of operations.

The 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 resulted in increased premiums and resulted in fewer covered individuals. Over time, 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, Overa and OVA1PLUS 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, and future regulation of LDTs may adversely affect commercialization of our diagnostic tests, which would negatively affect our results of operations and financial condition.

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. In January 13, 2017, the FDA released a Discussion Paper on LDTs and, in October 2017, the FDA released a draft guidance document outlining the FDA's proposal to actively regulate LDTs. 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.

In December 2018, Congress released a draft of the Verifying Accurate, Leading-edge IVCT Development ("VALID") Act, which incorporates FDA ideas for diagnostics regulation. This bill proposes a regulatory framework for IVDs and LDTs and would require premarket approval for *in vitro* clinical tests. If VALID is passed, we may fail to gain approval for some or all of our LDTs.

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.

The operation of ASPiRA LABS depends 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 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. The addition of our decentralized technology transfer business may also be affected by these information systems.

As the breadth and complexity of ASPiRA LABS' information system 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 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 or distributor 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. 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 14, 2020, five persons, in aggregate, beneficially owned approximately 62 million shares of our common stock, including the right to acquire approximately 3 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 61% 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, Overa, OVA1PLUS or ASPiRA GenetiX;
- 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, 2019, we had 97,286,157 shares of our common stock outstanding and 10,955,683 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 6,612,878 shares of our common stock that were subject to outstanding options. We also have warrants outstanding to purchase 2,810,338 shares of Vermillion common stock that were sold in conjunction with a private placement, which took place in February 2017.

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 and administrative offices	January 31, 2021
Trumbull, Connecticut	10,681 sq. ft.	Administrative offices	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. As of the date of the filing of this Form 10-K, we are not 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 April 2, 2020, there were 97 registered holders of record of our common stock. The closing price of our common stock on April 3, 2020 was $0.78.

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 Amended and Restated 2010 Stock Incentive Plan, as amended (the "2010 Plan") and the Vermillion, Inc. 2019 Stock Incentive Plan (the "2019 Plan").

2010 Plan. The authority of Vermillion's Board of Directors to grant new stock options and awards under the 2010 Plan terminated in 2019. The Board of Directors continued to administer the 2010 Plan with respect to the stock options that remained outstanding under the 2010 Plan. At December 31, 2019, options to purchase 6,405,878 shares of common stock remained outstanding under the 2010 Plan.

2019 Plan. The 2019 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 2019 Plan. The 2019 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 10,492,283 shares of Vermillion's common stock under the 2019 Plan. At December 31, 2019, options to purchase 207,000 shares of common stock remained outstanding under the 2019 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 2019 Plan as of December 31, 2019, 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	6,612,878	$ 1.40	10,955,683
Equity compensation plans not approved by security holders	-	-	-
Total	6,612,878		10,955,683

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.

In 2020, we plan to continue commercializing our new generation of technology and begin commercializing our decentralized technology transfer service platform. We also intend to raise public awareness regarding the diagnostic superiority of OVA1 as compared to cancer antigen ("CA125") for African American women with adnexal masses.

In the fourth quarter of 2018, we launched our new generation of technology, OVA1PLUS. OVA1PLUS is designed to improve accuracy and reduce false positive diagnoses by over 30% by leveraging the strengths of OVA1's sensitivity and Overa's specificity. OVA1PLUS will also be available through a decentralized platform structure enabling hospital networks and super groups to run the test in their labs.

We are focused on commercializing OVA1, Overa, OVA1PLUS and ASPiRA GenetiX both inside and outside the U.S. In 2018 and early 2019, 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 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 2020, 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 of diagnostic algorithms that will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value. The first diagnostic algorithm LDT, which we refer to internally as OVAnex, and formerly referred to as Diagnostic Algorithm #1 and Watch and Wait, focuses on monitoring women with pelvic masses. We expect OVAnex to be available for commercial use in 2021. The second diagnostic algorithm LDT, Endocheck, formerly known as Diagnostic Algorithm #2, will focus on endometriosis. We also plan to expand our portfolio of products to include OVAinherit, which is the basis for a high-risk screening test for those patients who are genetically predisposed to ovarian cancer. This algorithm will include genetics, proteins and other modalities to assess the risk. All of our products are focused on gynecologic diseases that cannot be assessed through a traditional biopsy.

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

We recognize product revenue in accordance with the provisions of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), all revenue is recognized upon completion of the OVA1, Overa or OVA1PLUS 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 review our patient account population and determine 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 of ASC 606, 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 and 2019 Plans. 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.

Liquidity

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 $13,488,000 after deducting offering expenses.

As discussed in Note 7, on June 28, 2019, the Company completed a public offering, pursuant to which certain investors purchased Vermillion common stock for net proceeds of approximately $13,521,000 after deducting underwriting discounts, commissions and other expenses related to the offering. On July 2, 2019, William Blair & Company, L.L.C., the sole underwriter of the Offering, exercised its option to purchase additional shares of Vermillion common stock for net proceeds of approximately $2,092,000, after deducting underwriting discounts, commissions and other expenses related to the offering.

We have incurred significant net losses and negative cash flows from operations since inception, and as a result have an accumulated deficit of approximately $422,161,000 at December 31, 2019. We expect to incur a net loss in 2020 as well. In order to continue our operations as currently planned through 2020 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 a primary investor when that investor 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

In January 2019, we announced that Cigna added OVA1®(MIA) to its national preferred coverage list.

In the first quarter of 2019, we began the development stage of our third-generation technology and first diagnostic algorithm LDT, internally known as OVAnex, and formerly referred to as Diagnostic Algorithm #1 and Watch and Wait. The new test will have strong sensitivity and specificity as well as a negative predictive value of greater than 99%, which will allow physicians to serially monitor women with a mass to delay or avoid unnecessary surgery. Tackling serial monitoring, which involves testing each patient two to four times a year, presents a new and potentially large market opportunity for us. The test will be initially launched as a serial monitoring LDT only, but the 2020 prospective monitoring study will be designed to enable us to submit for FDA clearance if we choose to do so. We anticipate conducting further population-based studies and, if all goes well with the 2020 prospective monitoring study, a 2021 product launch.

In June 2019, we announced that both BlueCross BlueShield of Texas and BlueCross BlueShield of Arizona began offering preferred coverage for OVA1®(MIA).

In June 2019, we launched ASPiRA GenetiX, which is genetic testing for specific women's health diseases, with a core focus on ovarian cancer. Our initial launch is an offering to detect hereditary breast and ovarian cancer syndrome ("HBOC") and Carrier screening, genetic screening for carriers of disease. Women who test positive for HBOC variants have a significantly elevated risk of developing ovarian cancer. ASPiRA GenetiX complements OVA1PLUS and is sold at the same call point as OVA1PLUS. In time, ASPiRA GenetiX testing results could be reported in a combined report with OVA1PLUS.

On August 2, 2019, 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 30, 2020, Vermillion was granted an additional 180-calendar day compliance period, or until July 27, 2020, to regain compliance with the minimum bid price requirement. There is no assurance that we will be able to regain compliance by the July 27, 2020 extended deadline, and there is no assurance that we will otherwise maintain compliance with this or any of the other Nasdaq continued listing requirements.

In the fourth quarter of 2019, we completed all outstanding service revenue contract commitments relating to our ASPiRA IVD subsidiary. The Company is no longer pursuing IVD contracts and has fulfilled all contractual obligations under previous contracts. All direct employees and contract labor have been terminated.

During 2019, we made considerable advancements in our state Medicaid coverage. We have added a total of nine state Medicaid plans to our list of plans with positive coverage.

In December 2019, we initiated a study with Einstein Medical Center to review the disparity in ovarian cancer detection in African-American women, as well as other ethnicities.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. The novel coronavirus has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID-19, the disease caused by the novel coronavirus, a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the coronavirus outbreak. This outbreak has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. In addition, many conventions and industry conferences have been canceled. As of the date of the filing of this annual report on Form 10-K, we expect the COVID-19 pandemic and actions taken to contain it to decrease our travel and convention-related expenses for 2020. We are taking several measures to minimize the impact of the current closures and quarantines. Our salespeople are experiencing limitations on their ability to physically visit physician offices. We are evaluating other means of coverage such as virtual sales rep meetings and leveraging social media. We believe any significant disruption, when and if experienced, could be temporary; however, there is uncertainty around when disruption might occur, the duration and potential impact. As a result, we are unable to estimate the potential impact on our operations or cash flows as of the date of this filing.

Results of Operations – Year Ended December 31, 2019 as compared to Year Ended December 31, 2018

The Company's selected summary financial and operating data for the years ended December 31, 2019 and 2018 were as follows:

	Year Ended December 31,		Increase (Decrease)	
(dollars in thousands)	2019	2018	Amount	%
Revenue:				
Product	$ 4,404	$ 2,772	$ 1,632	59
Genetics	22	-	22	-
Service	112	281	(169)	(60)
Total revenue	4,538	3,053	1,485	49
Cost of revenue:				
Product	2,378	2,044	334	16
Genetics	295	-	295	-
Service	670	1,098	(428)	(39)
Total cost of revenue	3,343	3,142	201	6
Gross profit / (loss)	1,195	(89)	1,284	(1,443)
Operating expenses:				
Research and development	1,018	550	468	85
Sales and marketing	9,645	5,642	4,003	71
General and administrative	5,810	5,052	758	15
Total operating expenses	16,473	11,244	5,229	47
Loss from operations	(15,278)	(11,333)	(3,945)	35
Interest (expense) / income, net	59	(22)	81	(368)
Other (expense) / income, net	(18)	(16)	(2)	13
Net loss	$ (15,237)	$ (11,371)	$ (3,866)	34

Product Revenue. Product revenue was approximately $4,404,000 for the year ended December 31, 2019 compared to $2,772,000 for the same period in 2018. Revenue for ASPiRA LABS' OVA1 is being recognized when the OVA1 test is being performed based on estimates of what we expect to ultimately realize. The 59% product revenue increase is due to an increase in tests performed compared to the prior year, as well as approximately $56,000 in upward adjustments to estimates to recognize revenue for services provided in a prior period.

The number of OVA1 tests performed increased 68% to 12,898 OVA1 tests during the year ended December 31, 2019 compared to 7,679 OVA1 tests for the prior year. The volume increase was primarily due to our commercialization investment.

Genetics Revenue. Genetics revenue was $22,000 for the year ended December 31, 2019. There was no genetics revenue in 2018 as ASPiRA GenetiX was launched in the second quarter of 2019. We expect genetics revenue to increase as genetics will be offered for a full year in 2020. Revenue for genetics is being recognized when the ASPiRA GenetiX test is being performed based on estimates of what we expect to ultimately realize.

Service Revenue. Service revenue was $112,000 for the year ended December 31, 2019 compared to $281,000 for the same period in 2018, a decrease of $169,000, or 60%. Service revenue decreased due to a wind up of our IVD services. We do not expect any additional service revenue in 2020. Revenue for ASPiRA IVD was recognized once certain revenue recognition criteria had 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 $2,378,000 for the year ended December 31, 2019 compared to $2,044,000 for the same period in 2018, representing an increase of $334,000, or 16%, due primarily to increased lab supply and shipping costs due to the increase in tests performed compared to the prior year.

Cost of Revenue - Genetics. Cost of product revenue, which consisted primarily of personnel costs and consulting expense after the launch of ASPiRA GenetiX, was $295,000 for the year ended December 31, 2019. There were no costs of revenue associated with genetics in 2018 as the product was launched in 2019.

Cost of Revenue - Service. Cost of service revenue was $670,000 for the year ended December 31, 2019 compared to $1,098,000 for the same period in 2018. The 39% decrease was due to the wind up of our ASPiRA IVD subsidiary.

Research and Development Expenses. Research and development expenses represent costs incurred to develop our technology pipeline 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 increased by $468,000, or 85%, for the year ended December 31, 2019 compared to the same period in 2018. This increase was mainly due to increases in clinical trials and consulting costs. We expect research and development expenses in 2020 to increase compared to those of 2019, as we continue to invest in OVAnex, Endocheck and OVAinherit.

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 our products. 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 $4,003,000, or 71%, for the year ended December 31, 2019 compared to the prior year. This increase was primarily due to an increase in personnel and personnel expenses as well as travel and entertainment expenses. We expect sales and marketing expenses to increase in future periods as we continue to 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 increased by $758,000, or 15%, for the year ended December 31, 2019 compared to the same period in 2018. The increase was primarily due to increased headcount and legal expenses. We expect general and administrative expenses in 2020 to remain flat compared to those of 2019.

Liquidity and Capital Resources

We plan to continue to expend resources in the selling and marketing of OVA1, Overa, OVA1PLUS and ASPiRA GenetiX and developing additional diagnostic tests.

As discussed in Note 7, on June 28, 2019, the Company completed a public offering (the “Offering”), pursuant to which certain investors purchased shares of Vermillion common stock for net proceeds of approximately $13,521,000 after deducting underwriting discounts, commissions and other expenses related to the offering. On July 2, 2019, William Blair & Company, L.L.C., the sole underwriter of the Offering, exercised its option to purchase additional shares of Vermillion common stock for net proceeds of approximately $2,092,000, after deducting underwriting discounts, commissions and other expenses related to the offering.

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 $13,488,000 after deducting offering expenses. The Series B convertible preferred stock was converted to common stock on June 21, 2018.

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.

On March 22, 2016, we entered into a loan agreement, (as amended, 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. On each of March 7, 2018

and April 3, 2020, we amended the Loan Agreement to adjust the future milestones which would allow us to continue to be eligible to borrow the remaining $2,000,000 based on our current expectation of employment. Under the terms of the Loan Agreement, we may be eligible for forgiveness of up to $1,500,000 of the principal amount of the loan if we achieve certain job creation and retention milestones on or before December 31, 2022. Conversely, if we are either unable to meet these job creation or retention milestones, namely, hiring 25 full-time employees with a specified average annual salary on or before December 31, 2020 or retaining such employees for a consecutive two-year period on or before December 31,2022, or do not maintain our Connecticut operations for a period of 10 years after the Loan Agreement date, 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 loan. 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.

The Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2019, we had an accumulated deficit of $422,161,000 and stockholders' equity of $8,738,000. On December 31, 2019, we had $11,703,000 of cash and cash equivalents and $3,978,000 of current liabilities. The Company expects to incur a net loss in 2020 as well. Working capital levels are not sufficient to fund operations as currently planned through 2020 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 within one year after the date the financial statements are filed.

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 2020. Additionally, the impact of COVID-19 on our liquidity for 2020 cannot be estimated as of the date of this filing. See Note 12 to our consolidated financial statements.

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, Overa, OVA1PLUS and ASPiRA GenetiX adoption by physicians and patients;
- the rate of product adoption by healthcare systems and large physician practices of the decentralized distribution agreements for OVA1, Overa and OVAIPLUS;
- the insurance payer community's acceptance of and reimbursement for OVA1, Overa, OVA1PLUS and ASPiRA GenetiX;
- 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, 2019 and December 31, 2018 were $11,703,000 and $9,360,000, respectively. At December 31, 2019 and 2018, working capital was $9,432,000 and $7,824,000, respectively.

Net cash used in operating activities was $12,966,000 for the year ended December 31, 2019, resulting primarily from $15,237,000 net loss incurred partially offset by $1,193,000 of stock-based compensation expense, a $971,000 increase in accounts payable, accrued liabilities and other liabilities and $333,000 of depreciation and amortization expense. Net cash used in operating activities also included $280,000 of cash used from other changes in operating assets and liabilities.

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 accounts payable, accrued liabilities and other liabilities. Net cash used in operating activities also included $163,000 of cash used from other changes in operating assets and liabilities.

Net cash used in investing activities was $132,000 for the year ended December 31, 2019, and $113,000 for the year ended December 31, 2018 due to purchases of property and equipment.

Net cash provided by financing activities was $15,441,000 for the year ended December 31, 2019, which consisted primarily of net proceeds from our June 2019 public offering of common stock.

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.

Off-Balance Sheet Arrangements

As of December 31, 2019, 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, 2019 and 2018, consolidated statements of operations for the years ended December 31, 2019 and 2018, consolidated statements of changes in stockholders' equity for the years ended December 31, 2019 and 2018, consolidated statements of cash flows for the years ended December 31, 2019 and 2018 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, 2019.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2019, 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, 2019. 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, 2019 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, 2019, 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.

None.

ITEM 9B. OTHER INFORMATION

On April 3, 2020, Vermillion entered into the Second Amendment to Assistance Agreement by and between the State of Connecticut Acting by the DECD and Vermillion (the "Amendment") effective as of April 3, 2020. The Amendment amends the Loan Agreement, pursuant to which the Company may borrow up to $4,000,000 from the DECD. An initial disbursement of $2,000,000 was made to Vermillion on April 15, 2016 under the Loan Agreement. The primary purpose of the Amendment is to amend the conditions of the loan, including the criteria for receiving additional disbursements and the criteria for loan forgiveness.

The Amendment changes the criteria for receiving the next $1,000,000 available under the Loan Agreement by reducing from 40 to 25 the number of full-time employees that the Company is required to hire, by changing the date on or before which the Company must meet this requirement from March 1, 2021 to December 31, 2020, and by increasing the required capital investment of the Company from $18,000,000 to $18,800,000. Although the criteria for receiving the final $1,000,000 available under the loan have not changed, such disbursement is also conditioned on the Company meeting the requirements above.

The Amendment also changes the criteria for loan forgiveness by reducing from 40 to 30 the number of full-time employees that the Company is required to hire and retain to be eligible for such forgiveness, by changing the date on or before which the Company must meet this requirement from March 1, 2021 to December 31, 2022, and by lowering the initial forgiveness available under the loan from $2,000,000 to $1,000,000. The Amendment also adds a second tier of $500,000 in loan forgiveness if the Company hires and retains 40 full-time employees by December 31, 2022.

The Amendment also changes the circumstances under which DECD may require early repayment of a portion or all of the loan by reducing from 40 to 25 the number of full-time employees that the Company is required to hire and retain to avoid such early repayment and by changing the earliest measurement date based on which the Company may be required to make any repayment from March 1, 2021 to December 31, 2020.

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 2020 (the "2020 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 2020 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 2020 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 2020 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 2020 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-20.

(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	Amended and Restated Promissory Note #1 by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective April 3, 2020					√
4.5	Amended and Restated Promissory Note #2 by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective April 3, 2020					√
4.6	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	
4.7	Form of Warrant, issued February 13, 2017	8-K	001-34810	99.1	February 17, 2017	
4.8	Form of Letter Agreement, by and between Vermillion, Inc. and certain warrant holders	8-K	001-34810	4.1	August 28, 2017	
4.9	Form of Indenture	S-3	333-221092	4.6	October 24, 2017	
4.10	Description of Vermillion, Inc.'s Securities Pursuant to Section 12 of the Securities Exchange Act of 1934					√
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.	S-1/A	333-32812	10.9	August 24, 2000	

	(formerly Ciphergen Biosystems, Inc.) and certain of its employees #				
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-K	001-34810	10.7	March 28, 2019
10.8	Form of Vermillion, Inc.'s Restricted Stock Award #	10-K	001-34810	10.8	March 28, 2019
10.9	Vermillion, Inc. 2019 Stock Incentive Plan #	8-K	001-34810	10.1	June 24, 2019
10.10	Employment Agreement between Vermillion, Inc. and Fred Ferrara dated April 1, 2015 #	8-K	001-34810	10.1	April 6, 2015
10.11	Employment Agreement between Vermillion, Inc. and Valerie B. Palmieri effective January 1, 2015 #	8-K	001-34810	99.1	December 17, 2014
10.12	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
10.13	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
10.14	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
10.15	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
10.16	Amendment No. 4 to Testing and Services Agreement, executed as of March 11, 2020 by and among Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated	8-K	001-34810	10.1	March 17, 2020
10.17	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
10.18	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
10.19	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
10.20	Employment Agreement between Vermillion, Inc. and Robert Beechey dated December 18, 2017 #	8-K	001-34810	10.1	December 20, 2017

10.21	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	
10.22	Second 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 April 3, 2020					√
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") as of December 31, 2019 and 2018, 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, 2019 and 2018, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

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 negative cash flows from operations 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
April 7, 2020

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

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 11,703	$ 9,360
Accounts receivable	924	786
Prepaid expenses and other current assets	758	550
Inventories	25	92
Total current assets	13,410	10,788
Property and equipment, net	353	608
Other assets	65	12
Total assets	$ 13,828	$ 11,408
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,158	$ 950
Accrued liabilities	2,588	1,825
Short-term debt	193	189
Other current liabilities	39	-
Total current liabilities	3,978	2,964
Long-term debt	1,099	1,292
Other non-current liabilities	13	-
Total liabilities	5,090	4,256
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, 2019 and 2018	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized; 97,286,157 and 75,501,394 shares issued and outstanding at December 31, 2019 and 2018, respectively	97	75
Additional paid-in capital	430,802	414,001
Accumulated deficit	(422,161)	(406,924)
Total stockholders' equity	8,738	7,152
Total liabilities and stockholders' equity	$ 13,828	$ 11,408

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,	
	2019	**2018**
Revenue:		
Product	$ 4,404	$ 2,772
Genetics	22	-
Service	112	281
Total revenue	4,538	3,053
Cost of revenue:[1]		
Product	2,378	2,044
Genetics	295	-
Service	670	1,098
Total cost of revenue	3,343	3,142
Gross profit / (loss)	1,195	(89)
Operating expenses:		
Research and development[2]	1,018	550
Sales and marketing[3]	9,645	5,642
General and administrative[4]	5,810	5,052
Total operating expenses	16,473	11,244
Loss from operations	(15,278)	(11,333)
Interest (expense) income, net	59	(22)
Other (expense) / income, net	(18)	(16)
Net loss	$ (15,237)	$ (11,371)
Net loss per common share - basic and diluted	$ (0.18)	$ (0.16)
Weighted average common shares used to compute basic and diluted net loss per common share	86,595,581	70,085,842
Non-cash stock-based compensation expense included in expenses:		
(1) Cost of revenue	$ 78	$ 124
(2) Research and development	4	6
(3) Sales and marketing	125	102
(4) General and administrative	986	869

See accompanying Notes to Consolidated Financial Statements

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

See accompanying Notes to Consolidated Financial Statements

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
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
Net loss	-	-	-	-	-	(15,237)	(15,237)
Common stock issued in conjunction with public offering, net of $1,480 in issuance costs	-	-	18,750,000	19	13,502	-	13,521
Common stock issued in conjunction with exercise of stock options	-	-	19,687	-	17	-	17
Common stock issued for restricted stock awards	-	-	202,576	-	250	-	250
Stock compensation charge	-	-	-	-	943	-	943
Common stock issued in conjunction with the exercise of the underwriter's option to purchase additional shares in connection with a public offering, net of $158 in issuance costs	-	-	2,812,500	3	2,089	-	2,092
Balance at December 31, 2019	-	$ -	97,286,157	$ 97	$ 430,802	$ (422,161)	$ 8,738

See accompanying Notes to Consolidated Financial Statements

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

	Year Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (15,237)	$ (11,371)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	333	675
Stock-based compensation expense	1,193	1,101
Loss on sale and disposal of property and equipment	54	11
Changes in operating assets and liabilities:		
Accounts receivable	(138)	(81)
Prepaid expenses and other assets	(209)	(92)
Inventories	67	10
Accounts payable, accrued liabilities and other liabilities	971	380
Net cash used in operating activities	(12,966)	(9,367)
Cash flows from investing activities:		
Purchase of property and equipment	(133)	(113)
Proceeds of property and equipment	1	-
Net cash used in investing activities	(132)	(113)
Cash flows from financing activities:		
Proceeds from public offering of preferred stock, net of issuance costs	-	4,496
Proceeds from public offering of common stock, net of issuance costs	13,521	8,990
Proceeds from issuance of common stock in conjunction with the exercise of the underwriter's option to purchase additional shares in connection with a public offering, net of issuance costs	2,092	-
Principal repayment of DECD loan	(189)	(185)
Repayment of capital lease obligations	-	(29)
Proceeds from issuance of common stock from exercise of stock options	17	29
Net cash provided by financing activities	15,441	13,301
Net increase in cash and cash equivalents	2,343	3,821
Cash and cash equivalents, beginning of year	9,360	5,539
Cash and cash equivalents, end of year	$ 11,703	$ 9,360
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	38	44
Non-cash investing and financing activities:		
Net increase in other assets/other liabilities for right of use assets	52	-

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™, Overa™ and Ova1PLUS™ risk of malignancy tests for ovarian cancer ("OVA1", "Overa" and "OVA1PLUS," respectively) through Vermillion's wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, Inc. ("ASPiRA LABS"). The Company also recently launched genetic testing for specific women's health diseases, called ASPiRA GenetiX, with a core focus on ovarian cancer.

The Company also offered in-vitro diagnostic ("IVD") trial services to third-party customers through its wholly-owned subsidiary, ASPiRA IVD, Inc. ("ASPiRA IVD"), which commenced operations in June 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. The Company stopped pursuing contracts through ASPiRA IVD in 2019. All contracts and obligations of ASPiRA IVD had been fulfilled. The Company's only remaining obligation as of December 31, 2019, with respect to ASPiRA IVD, is to furnish documents that support work done during customer trials upon request. Upon closure of ASPiRA IVD's business, the Company evaluated common costs that would remain with the business after the closure. It was determined that approximately $260,000 of the Company's costs that were previously allocated to the ASPiRA IVD subsidiary, including cost of revenue, would not be eliminated with the closure. The Company also retired assets with a net book value of approximately $50,000 relating to the closure of the business. These assets included leasehold improvements used to build out the lab as well as some specialized equipment that could not be repurposed to other areas of the Company.

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 (the "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.

As discussed in Note 7, on April 17, 2018, the Company completed two public offerings (the "2018 Offerings"), pursuant to which certain investors purchased Vermillion common stock and Vermillion Series B convertible preferred stock for net proceeds of approximately $13,488,000 after deducting offering expenses.

As discussed in Note 7, on June 28, 2019, the Company completed a public offering (the "Offering"), pursuant to which certain investors purchased Vermillion common stock for net proceeds of approximately $13,521,000 after deducting underwriting discounts, commissions and other expenses related to the offering. On July 2, 2019, William Blair & Company, L.L.C., the sole underwriter of the Offering, exercised its option to purchase additional shares of Vermillion common stock for net proceeds of approximately $2,092,000, after deducting underwriting discounts, commissions and other expenses related to the offering.

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 $422,161,000 at December 31, 2019. The Company expects to incur a net loss in 2020 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 sales and licensing to be the Company's only material, recurring source of cash in 2020. Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date these financial statements are filed. 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: The Company recognizes product revenue in accordance with the provisions of ASC 606. Product revenue is recognized upon completion of the OVA1, Overa or OVA1PLUS test and delivery of results to the physician 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 reviews its patient account population and determines 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. During the year ended December 31, 2019, there were adjustments to estimates to recognize revenue for services provided in a prior period totaling a net of approximately $56,000. There were no impairment losses on accounts receivable recorded during the years ended December 31, 2019 or 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.

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.

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.

Genetics Revenue: Under ASC 606, the Company's genetics revenue is recognized upon completion of the ASPiRA GenetiX test and delivery of results 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 there is not significant history on which to rely.

Service Revenue: The Company's service revenue was 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.

Measurement of progress on contracts with customers was generally 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 $203,000 and $219,000 for the years ended December 31, 2019 and 2018, respectively.

Stock-Based Compensation

The Company records the fair value of non-cash stock-based compensation costs for stock options 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 requisite service period of the award, which is generally equal to the vesting period. 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 records stock-based compensation net of estimated forfeitures.

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

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

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

Net Loss Per Share

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

Fair Value of Financial Instruments

Financial instruments include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and 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 operating and 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 adopted the standard on January 1, 2019, and the adoption did not have a material impact on the consolidated financial statements.

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 2023 for smaller reporting companies. 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, in July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), which provides a number of optional practical 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. The Company has also elected to use the hindsight practical expedient. The Company has two office leases which are required to be recorded as ROU assets and corresponding lease liabilities on the balance sheet. The Company has one short-term lease with a term of twelve months. The Company has elected the policy of not recording leases on the balance sheet when the leases have terms of 12 months or less. The Company recognized ROU assets and a lease liability of approximately $178,000 related to its leases on its consolidated balance sheet as of January 1, 2019. The Company did 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.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal Use Software: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a cloud computing arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 is effective for annual and interim periods beginning after December 15, 2019, with early adoption permitted. The Company adopted ASU 2018-15 effective on January 1, 2020, using the prospective transition approach, which allows the Company to change the accounting method without restating prior periods or booking cumulative adjustments. The adoption of ASU 2018-15 did not have a material impact on the consolidated financial statements.

NOTE 3: Strategic Alliance with Quest Diagnostics Incorporated

In March 2015, the Company reached an agreement with Quest Diagnostics, Incorporated ("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 11, 2020, 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.

Note 4: Property and Equipment

The components of property and equipment as of December 31, 2019 and 2018 were as follows**:**

	December 31,	
(in thousands)	**2019**	**2018**
Machinery and equipment	$ 841	$ 1,367
Demonstration equipment	16	39
Computer equipment and software	1,094	1,109
Furniture and fixtures	144	137
Leasehold improvements	639	706
Gross property and equipment	2,734	3,358
Accumulated depreciation and amortization	(2,381)	(2,750)
Property and equipment, net	$ 353	$ 608

Depreciation expense for property and equipment was $333,000 and $675,000 for the years ended December 31, 2019 and 2018, respectively.

NOTE 5: Accrued Liabilities

The components of accrued liabilities as of December 31, 2019 and 2018 were as follows:

	December 31,	
(in thousands)	**2019**	**2018**
Payroll and benefits related expenses	$ 1,229	$ 853
Collaboration and research agreements expenses	350	366
Professional services	679	329
Other accrued liabilities	330	277
Total accrued liabilities	$ 2,588	$ 1,825

NOTE 6: Commitments, Contingencies and debt

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. On each of March 7, 2018 and April 3, 2020, the Company amended the Loan Agreement to adjust the future milestones which would allow the Company to continue to be eligible to borrow the remaining $2,000,000 based on its current expectation of employment. The amended agreement changes the criteria for receiving the next $1,000,000 available under the Loan Agreement by reducing from 40 to 25 the number of full-time employees that the Company is required to hire, by changing the date on or before which the Company must meet this requirement from March 1, 2021 to December 31, 2020, and by increasing the required capital investment of the Company from $18,000,000 to $18,800,000. Although the criteria for receiving the final $1,000,000 available under the loan have not changed, such disbursement is also conditioned on the Company meeting the requirements above.

Under the terms of the Loan Agreement, as amended, the Company may be eligible for forgiveness of up to $1,500,000 of the principal amount of the loan if the Company achieves certain job creation and retention milestones by December 31, 2022 (the "Measurement Date"). Conversely, if the Company is either unable to meet these job creation and retention milestones, namely, hiring 25 full-time employees with a specified average annual salary on or before December 31, 2020 or retaining such employees for a consecutive two-year period or does not maintain the Company's Connecticut operations for a period of 10 years after the Loan Agreement date, 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 loan.

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, net of issuance costs, was $1,292,000 and $1,481,000 at December 31, 2019 and 2018, respectively.

As of December 31, 2019, the annual amounts of future minimum principal payments due under certain of the Company's contractual obligations are shown in the table below.

	Payments Due by Period						
(in thousands)	**Total**	**2020**	**2021**	**2022**	**2023**	**2024**	**Thereafter**
Debt Obligations	1,314	197	200	205	209	213	290
Total	$ 1,314	$ 197	$ 200	$ 205	$ 209	$ 213	$ 290

In addition, the Company has minimum royalty obligations (described below in non-cancelable collaboration obligations and other commitments) and annual minimum quantities of reagent purchases from the manufacturer of certain laboratory instruments of approximately $178,000.

Operating Leases

The Company leases facilities to support its business of discovering, developing and commercializing diagnostic tests in the fields of gynecologic disease. The Company's principal facility, including the CLIA laboratory used by ASPiRA LABS, is located in Austin, Texas. The CLIA laboratory that was used by ASPiRA IVD is located in Trumbull, Connecticut. The Company's Austin, Texas lease expires on January 31, 2020. The Company has elected to extend the lease for a term of twelve months. The new Austin, Texas lease expires on January 31, 2021.

In October 2015, the Company entered into a lease agreement for a facility in Trumbull, Connecticut. The lease required initial payments for the buildout of leasehold improvements to the office space, which were approximately $596,000. The Company has the right to renew the lease for up to two five-year terms at a rate equal to 90% of the then-current fair market rate. The

Company's Trumbull, Connecticut lease expires on June 8, 2021. The Company is not reasonably certain to exercise the renewal option for its Trumbull, Connecticut lease due to the uncertain nature of its pricing.

The expense associated with these operating leases for the years ended December 31, 2019 and 2018 is shown in the table below (in thousands).

		Year Ended December 31	
Lease Cost	**Classification**	**2019**	**2018**
Operating rent expense			
	Cost of revenue	$ 38	$ 100
	Research and development	11	27
	Sales and marketing	35	49
	General and administrative	46	89
Variable rent expense			
	Cost of revenue	$ 49	$ 1
	Research and development	14	0
	Sales and marketing	41	1
	General and administrative	57	2

Based on our leases as of December 31, 2019, the table below sets forth the approximate future lease payments related to operating leases with initial terms of one year or more (in thousands).

2020	40
2021	14
Total Operating Lease Payments	54
Less: Interest	(2)
Present Value of Lease Liabilities	$ 52

Non-cancelable Collaboration Obligations and Other Commitments

The Company is a party to an amended research collaboration agreement with The Johns Hopkins University School of Medicine under which the Company licenses certain of its intellectual property directed at the discovery and validation of biomarkers in human subjects, including but not limited to clinical application of biomarkers in the understanding, diagnosis and management of human disease. Under the terms of the amended research collaboration agreement, Vermillion is required to pay the greater of 4% royalties on net sales of diagnostic tests using the assigned patents or annual minimum royalties of $57,500. Royalty expense for the years ended December 31, 2019 and 2018 totaled $176,000 and $120,000, 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

2019 Offering

On June 26, 2019, the Company entered into an underwriting agreement (the "Underwriting Agreement") with William Blair & Company, L.L.C., as the sole underwriter (the "Underwriter"), in connection with the underwritten public offering of 18,750,000 shares of the Company's common stock, par value $0.001 per share.

Pursuant to the Underwriting Agreement, the Company agreed to issue and sell an aggregate of 18,750,000 shares of Vermillion common stock offered by the Underwriter in a public offering at a price of $0.80 per share (the "Offering"). The Offering

closed on June 28, 2019 and resulted in net proceeds to the Company of approximately $13,521,000, after deducting expenses of approximately $1,500,000.

Under the Underwriting Agreement, the Company granted the Underwriter an option to purchase up to an additional 2,812,500 shares of Vermillion common stock at the public offering price, less underwriting discounts and commissions. On July 2, 2019, the Underwriter exercised its option to purchase 2,812,500 shares of Vermillion common stock at a price of $0.80 per share and resulted in proceeds to the Company of approximately $2,092,000, after deducting underwriting discounts, commissions and other expenses related to the offering.

2018 Offerings

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

Pursuant to the first 2018 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 2018 Underwriter in a public offering at a price to the public of $1.00 per share (the "2018 Common Stock Offering"). Under this 2018 Underwriting Agreement, the Company granted the 2018 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 2018 Underwriter did not exercise this option. The 2018 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 2018 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 2018 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.

Stockholders 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, this 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, 2019 and 2018 were as follows:

Issuance Date	Expiration Date	Exercise Price per Share	Number of Shares Outstanding under Warrant December 31, 2019	Number of Shares Outstanding under Warrant December 31, 2018
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, 2019 and 2018 was as follows:

(In thousands, except per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
Year ended December 31, 2018:			
Net loss available to common shareholders - basic	$ (11,371)	70,085,342	$ (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)	70,085,342	$ (0.16)
Year ended December 31, 2019:			
Net loss available to common shareholders - basic	$ (15,237)	86,595,581	$ (0.18)
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	$ (15,237)	86,595,581	$ (0.18)

Due to net losses for the years ended December 31, 2019 and 2018, 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, 2019 and 2018 were as follows:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Stock options	6,612,878	4,612,005
Stock warrants	2,810,338	2,810,338
Unvested restricted stock awards	-	11,667
Potential common shares	9,423,216	7,434,010

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 years ended December 31, 2019 or 2018. 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 were eligible to receive 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 2018, Vermillion's stockholders approved increases 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. The authority of Vermillion's Board of Directors to grant new stock options and awards under the 2010 Plan terminated in 2019. Vermillion's Board of Directors continued to administer the 2010 Plan with respect to the stock options that remained outstanding under the 2010 Plan. Options to purchase 19,687 shares of common stock were exercised during the year ended December 31, 2019. Options to purchase 32,500 shares of common stock were exercised during the year ended December 31, 2018. During the year ended December 31, 2019, Vermillion issued to Vermillion's Board of Directors 190,909 shares of restricted stock under the 2010 Plan having a fair value of $252,000 as payment for services rendered in 2019. Vermillion also issued to certain consultants 11,667 shares of restricted stock under the 2010 Plan having a fair value of $4,000. During the year ended December 31, 2018, Vermillion issued to Vermillion's Board of Directors an aggregate 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.

2019 Stock Incentive Plan

At Vermillion's 2019 annual meeting of stockholders, the Company's stockholders approved the Vermillion, Inc. 2019 Stock Incentive Plan (the "2019 Plan"). The purposes of the 2019 Plan are (i) to align the interests of the Company's stockholders and recipients of awards under the 2019 Plan by increasing the proprietary interest of such recipients in the Company's growth and success; (ii) to advance the interests of the Company by attracting and retaining non-employee directors, officers, other employees, consultants, independent contractors and agents; and (iii) to motivate such persons to act in the long-term best interests of the Company and its stockholders. The 2019 Plan allows the Company to grant stock options, stock appreciation rights, restricted stock, restricted stock units and performance awards to participants.

Subject to the terms and conditions of the 2019 Plan, the initial number of shares authorized for grants under the 2019 Plan is 10,492,283. To the extent an equity award granted under the 2019 Plan or the 2010 Plan expires or otherwise terminates without having been exercised or paid in full, or is settled in cash, the shares of common stock subject to such award will become available for future grant under the 2019 Plan. As of December 31, 2019, a total of 10,492,283 shares of common stock had been reserved for issuance under the 2019 Plan, of which 207,000 shares of common stock are subject to outstanding stock options.

The activity related to shares available for grant under the 2000 Plan, the 2010 Plan and the 2019 Plan for the years ended December 31, 2019 and 2018 was as follows:

	2000 Stock Plan	2010 Stock Option Plan	2019 Stock Option Plan	Total
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
Shares added	-	-	8,000,000	8,000,000
Shares transferred	-	(2,492,283)	2,492,283	-
Options canceled	-	691,025	-	691,025
Options granted	-	(2,504,585)	(207,000)	(2,711,585)
Restricted stock units granted	-	(202,576)	-	(202,576)
Shares available at December 31, 2019	-	670,400	10,285,283	10,955,683

The stock option activity under the 2000 Plan, the 2010 Plan and the 2019 Plan for the years ended December 31, 2019 and 2018 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
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
Granted	2,711,585	1.02		
Exercised	(19,687)	1.32		
Canceled	(691,025)	1.79		
Options outstanding at December 31, 2019	6,612,878	$ 1.67	$ 303,995	8.66
Shares exercisable:				
December 31, 2019	3,115,001	$ 1.69	$ 15,026	5.95
Shares expected to vest:				
December 31, 2019	2,868,259	$ 1.14	$ 288,969	8.66

The range of exercise prices for options outstanding and exercisable at December 31, 2019 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	3,769,835	$ 1.02	8.81	851,710	$ 1.13
1.31 - 1.64	1,144,168	1.49	4.97	974,418	1.48
1.65 - 2.08	791,000	1.99	5.21	709,998	1.99
2.09 - 11.55	907,875	2.35	6.37	578,875	2.48
$ 0.01 - $ 11.55	6,612,878	$ 1.40	7.38	3,115,001	$ 1.69

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2019	$ 8	$ 2,869
Year ended December 31, 2018	$ 9	$ 2,319

Stock-based Compensation

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 and the 2019 Plan that were incorporated in the Black-Scholes pricing model for the years ended December 31, 2019 and 2018 were as follows:

	Year Ended December 31,	
	2019	**2018**
Dividend yield	- %	- %
Volatility	79 %	69 %
Risk-free interest rate	2.30 %	2.69 %
Expected lives (years)	4.0	4.0
Weighted average grant date fair value	$ 0.55	$ 0.51

The allocation of employee and director stock-based compensation expense by functional area for the years ended December 31, 2019 and 2018 was as follows:

	Year Ended December 31,	
(in thousands)	**2019**	**2018**
Cost of sales	$ 67	$ 91
Research and development	4	6
Sales and marketing	122	112
General and administrative	942	982
Total	$ 1,135	$ 1,191

As of December 31, 2019, total unrecognized compensation cost related to unvested stock option awards was approximately $1,633,000 and the related weighted average period over which it is expected to be recognized was 2.54 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, 2019 and 2018, the Company did not contribute to the 401(k) Plan.

NOTE 10: Income Taxes

There was no income tax expense or benefit for the years ended December 31, 2019 or 2018 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 believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2019 and 2018.

The components of net deferred tax assets (liabilities) at December 31, 2019 and 2018 were as follows:

	Year Ended December 31,	
(in thousands)	2019	2018
Deferred tax assets:		
Net operating losses	$ 21,024	$ 20,614
Amortization - R&D intangibles	1,903	2,410
Other	11,577	2,406
Total deferred tax assets	34,504	25,430
Valuation allowance	(34,504)	(25,430)
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, 2019 and 2018 was as follows:

	Year Ended December 31,	
	2019	2018
Tax at federal statutory rate	21 %	21 %
State tax, net of federal benefit	2	1
Valuation allowance	(19)	(19)
Permanent items	(1)	-
Change in Federal Tax Rate (2017 Tax Reform)	-	2
Other	(3)	(5)
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 generates 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 believes 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.

Legislation 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 believes 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 $34,500,000 and $25,400,000 at December 31, 2019 and 2018, respectively. The increase of approximately $9,100,000 between 2018 and 2019 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, 2019, the Company's federal returns for the years ended 2016 through the current period and most state returns for the years ended 2015 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 2016 and 2015, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2018 reflect research and development carryforwards of $5,427,000 and $5,330,000, respectively. The Company has recognized additional deferred tax assets for federal and California research and development credits of $0 and $21,000 for the year ended December 31, 2019, respectively.

As of December 31, 2019, the Company's gross unrecognized tax benefits are approximately $10,644,000 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, 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 during 2018	-	-	-
Balance at December 31, 2018	$ 5,637	$ 5,330	$ 10,967
Return to provision true up	(210)	-	(210)
Increase in tax position during 2019	-	21	21
Decrease due to expirations during 2019	(134)	-	(134)
Balance at December 31, 2019	$ 5,293	$ 5,351	$ 10,644

The increase for the year ended December 31, 2019 relates to a position taken in the current year. The increase for the year ended December 31, 2018 is related to tax positions taken during 2018 and prior years. If the $10,644,000 of unrecognized income tax benefit is recognized, approximately $10,644,000 would impact the effective tax rate in the period in which each of the benefits is recognized.

The Company recognizes interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations and comprehensive loss. The Company has not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2019 and 2018. 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 years ended December 31, 2019 and 2018, the consultant was paid an aggregate of $0 and $53,925 for services provided pursuant to the consulting agreement.

NOTE 12: SUBSEQUENT EVENTS

On February 19, 2020, the Company finalized an in-network contract agreement with CIGNA. This agreement includes OVA1 and Overa, as well as our ovarian and carrier genetics testing panels. The final agreed prices will be effective April 1, 2020.

On March 11, 2020, the World Health Organization declared the outbreak of the novel coronavirus ("COVID-19") a global pandemic, which continues to spread throughout the United States and around the world. This outbreak has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. In addition, many conventions and industry conferences have been canceled. As of the date of the filing of this annual report on Form 10-K, the Company expects the COVID-19 pandemic and actions taken to contain it to decrease our travel and convention-related expenses for 2020. The Company is taking several measures to minimize the impact of the current closures and quarantines. The Company's salespeople are experiencing limitations on their ability to physically visit physician offices. The Company is evaluating other means of coverage such as virtual sales rep meetings and leveraging social media. While these disruptions could be temporary, continued disruption may negatively impact sales for 2020 and the Company's overall liquidity. The full impact of COVID-19 continues to evolve as the date of this filing. As a result, the Company is not able to estimate the effects of COVID-19 on its results of operations, financial condition, or liquidity for 2020.

On March 27, 2020, the U.S federal government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The CARES Act is an emergency economic stimulus package in response to the coronavirus outbreak which, among other things, contains numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. The Company is currently evaluating the implications of the CARES Act, and its impact on the financial statements and related disclosures has not yet been determined.

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: April 7, 2020

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

Date: April 7, 2020

/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	April 7, 2020
/s/ Robert Beechey Robert Beechey	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 7, 2020
/s/ James T. LaFrance James T. LaFrance	Chairman of the Board of Directors	April 7, 2020
/s/ James S. Burns James S. Burns	Director	April 7, 2020
/s/ Nancy Cocozza Nancy Cocozza	Director	April 7, 2020
/s/ Veronica G. H. Jordan Veronica G. H. Jordan	Director	April 7, 2020
/s/ David Schreiber David Schreiber	Director	April 7, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Introduction

Vermillion, Inc. (the "Company," "we," "us" or "our") has one security registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, which is our common stock. Our common stock is listed on The Nasdaq Capital Market under the symbol "VRML."

The following summary does not purport to be complete and is qualified by reference to certain provisions of the Delaware General Corporation Law, as amended (the "DGCL"), our Fourth Amended and Restated Certificate of Incorporation, dated January 22, 2010, as amended effective June 19, 2014 (our "Certificate of Incorporation"), and our Fifth Amended and Restated Bylaws, effective June 19, 2014 (our "Bylaws"), each of which has been filed as an exhibit to the Annual Report on Form 10-K filed with the Securities and Exchange Commission to which this exhibit is attached and is hereby incorporated by reference.

Authorized Capital Stock

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share.

Preferred Stock

Our board of directors is authorized, subject to any limitations prescribed by law, without stockholder approval, to issue from time to time up to an aggregate of 5,000,000 shares of preferred stock, in one or more series, each of such series to have such rights and preferences, including voting rights, dividend rights, conversion rights, redemption terms and liquidation preferences as shall be determined by our board of directors. Any issuance of shares of preferred stock could adversely affect the voting power or rights of holders of common stock, and 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.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters to be voted upon by the stockholders, and there are no cumulative voting rights. In all matters other than the election of directors, stockholder approval requires the affirmative vote of the majority of the holders of our common stock entitled to vote on the subject matter unless the matter is one upon which, by express provision of law, our Certificate of Incorporation or our Bylaws, a different vote is required. Directors are elected by a plurality of the votes of the shares present in person or represented by proxy and entitled to vote on the election of directors.

Dividend Rights

Subject to preferences to which holders of preferred stock may be entitled and the rights of certain of our stockholders set forth in the Stockholders Agreement (as defined below), holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available therefor. 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. We intend to retain all available funds and any future earnings to fund the development and expansion of our business.

No Preemptive or Similar Rights

Holders of our common stock do not have preemptive rights, and our common stock is not convertible or redeemable. As described under "Stockholders Agreement," certain holders of our common stock have the right to purchase shares in connection with most equity offerings made by the Company.

Right to Receive Liquidation Distributions

In the event of our liquidation, dissolution or winding up, holders of common stock would be entitled to share in our assets remaining after the payment of liabilities and the satisfaction of any liquidation preference granted the holders of any outstanding shares of any senior class of securities. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate in the future.

Stockholders Agreement

In connection with a private placement in May 2013, we entered into a stockholders agreement with the purchasers named therein (the "Stockholders Agreement"). Pursuant to and subject to the terms of the Stockholders Agreement, certain of the investors received rights to participate in any future equity offerings on the same price and terms as other investors, and rights to exercise "piggyback" registration rights for any registration statements that we file prior to May 13, 2018 on our own account or for the account of others with respect to shares of our common stock.

In addition, the Stockholders Agreement prohibits the Company from taking material actions without the consent of at least one of the two primary investors. These material actions include:

- making any acquisition with value greater than $2 million;
- entering into, or amending the terms of agreements with Quest Diagnostics, provided that such investors' consent shall not be unreasonably withheld, conditioned or delayed following good faith consultation with the Company;
- submitting any resolution at a meeting of stockholders or in any other manner changing or authorizing a change in the size of our board of directors;
- offering, selling or issuing any securities senior to our common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to our common stock;
- amending our Certificate of Incorporation or our Bylaws in any manner that affects the rights, privileges or economics of our common stock or the warrants purchased in the May 2013 private placement;
- taking any action that would result in a change in control of Vermillion or an insolvency event;
- paying or declaring dividends on any securities of the Company or distributing any assets of the Company other than in the ordinary course of business or repurchasing any outstanding securities of the Company; or
- adopting or amending any stockholder rights plan.

In addition, the two primary investors (Jack W. Schuler, on the one hand, and Oracle Partners, LP and Oracle Ten Fund Master, LP, on the other hand) each received the right to designate a person to serve on our board of directors. These rights terminate for each investor when that investor 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 such investor purchased at the closing of our May 2013 private placement.

Section 203 of the Delaware Corporation Law

We are subject to Section 203 of the DGCL, which prevents an "interested stockholder" (defined in Section 203 of the DGCL, generally, as a person owning 15% or more of a corporation's outstanding voting stock), from engaging in a "business combination" (as defined in Section 203 of the DGCL) with a publicly-held Delaware corporation for three years following the date such person became an interested stockholder, unless:

- before such person became an interested stockholder, the board of directors of the corporation approved the transaction in which the interested stockholder became an interested stockholder or approved the business combination;
- upon consummation of the transaction that resulted in the interested stockholders becoming an interested stockholder, the interested stockholder owns at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (excluding stock held by directors who are also officers of the corporation and by employee stock plans that do not provide employees with the rights to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer); or
- following the transaction in which such person became an interested stockholder, the business combination is approved by the board of directors of the corporation and authorized at a meeting of stockholders by the affirmative vote of the holders of two-thirds of the outstanding voting stock of the corporation not owned by the interested stockholder.

The provisions of Section 203 of the DGCL could make a takeover of the Company difficult.

Effect of Certain Provisions of Our Certificate of Incorporation and Bylaws

Certain provisions of our Certificate of Incorporation and Bylaws may also 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. 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 authorizes undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us.

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 our Certificate of Incorporation described in the immediately preceding paragraph would require approval by our board of directors and the affirmative vote of at least 66 2/3% of our then outstanding voting securities, and the amendment of any of the provisions of our Bylaws described in the immediately preceding paragraph would require approval by our board of directors or the affirmative vote of at least 66 2/3% of our then outstanding voting securities.

Exhibit 4.4

AMENDED AND RESTATED PROMISSORY NOTE #1

$2,000,000.00 April 3, 2020

Trumbull, Connecticut

FOR VALUE RECEIVED, the undersigned, **VERMILLION, INC.,** a Delaware corporation authorized to conduct business in the State of Connecticut, with an office and principal place of business located at 12117 Bee Caves Road, Building III, Suite 100, Austin, Texas 78738 (the "Applicant"), promises to pay to the order of the STATE OF CONNECTICUT, acting by and through its DEPARTMENT OF ECONOMIC AND COMMUNITY DEVELOPMENT ("State"), at its office at 505 Hudson Street, Hartford, Connecticut 06106 or at such other place as the holder hereof (including State, hereinafter referred to as "Holder") may designate, the sum of TWO MILLION 00/100 DOLLARS ($**2,000,000.00**) or such lesser amount as may be due and payable to State under the terms and conditions of that certain Assistance Agreement dated March 22, 2016, as amended by a First Amendment to Assistance Agreement dated March 7, 2018, and as further amended by Second Amended and Restated Agreement of even date herewith by and between Applicant and State (collectively, the "Assistance Agreement"), the terms of which are incorporated by reference herein, together with interest on the unpaid balance of this Note at the rate set forth in Section 2(a) hereof, which interest shall be computed and payable as set forth therein, together with all taxes levied or assessed on this Note or the debt evidenced hereby against the Holder, and together with all reasonable costs, expenses and reasonable attorneys' and other reasonable professionals' fees incurred in any action to collect and/or enforce this Note or to enforce, protect, preserve, defend, realize upon or foreclose any security agreement, or other agreement securing or relating to this Note, including without limitation, all reasonable costs and expenses incurred to enforce, protect, preserve, defend or sustain the lien of said security agreement, or other agreement or in any litigation or controversy arising from or connected in any manner with said security agreement, or other agreement, or this Note. Applicant further agrees to pay all reasonable costs, expenses and reasonable attorneys' and other reasonable professionals' fees incurred by Holder in connection with any "workout" or default resolution negotiations involving legal counsel or other professionals and further in connection with any re-negotiation or restructuring of the indebtedness evidenced by this Note. Any such costs, expenses and/or fees remaining unpaid after demand therefor, may, at the discretion of the Holder, be added to the principal amount of the indebtedness evidenced by this Note.

All capitalized terms not otherwise defined herein shall have the meanings ascribed to such terms in the Assistance Agreement.

This Note has been executed and delivered subject to the following terms and conditions:

1. Lawful Interest. Notwithstanding any provisions of this Note, it is the understanding and agreement of the Applicant and Holder that the maximum rate of interest to be paid by Applicant to Holder shall not exceed the highest or the maximum rate of interest permissible to be charged under the laws of the State of Connecticut. Any amounts paid in excess of such rate shall be considered to have been payments in reduction of principal.

2. Payments of Principal and Interest.

(a) The principal amount of this Note shall bear interest at a rate of two percent (2%) per annum (the "Loan Interest Rate") commencing on the date on which the initial advance in respect of the Loan is funded (the "Advancement Date"). Commencing on the first day of the second month following the Advancement Date, which was April 15, 2016, and continuing on the same day of each and every month thereafter until the date which is ten (10) years from the first day of the month following the Advancement Date (the "Maturity Date"), and so long as no Instance of Default shall have occurred and remains uncured past any applicable cure period, principal and interest under this Note shall be payable in one hundred twenty (120) equal monthly installments in such a manner as to fully amortize the Loan over the remaining term of this Note.

(b) The entire indebtedness under this Note, including, all outstanding principal (including amounts not forgiven or repaid), accrued and unpaid interest, if any, and any other obligations due hereunder or under the Assistance Agreement, shall be due and payable in full on the Maturity Date.

(c) Payments in respect of this Note shall be made payable to "The State of Connecticut, Department of Economic and Community Development".

1. Late Charge. In the event Applicant fails to pay any installment of principal and/or interest within fifteen (15) days of the date when said amount was due and payable, without in any way affecting the Holder's right to accelerate this Note, a late charge equal to five percent (5.00%) of such late payment shall, at the option of Holder, be assessed against Applicant and be due upon demand by the Holder.

4. Prepayments. The Applicant may prepay principal of this Note, in whole or in part, at any time without penalty or premium. Any and all prepayments shall be applied first to accrued and unpaid interest and then to unpaid principal in the inverse order of maturity, and shall not affect the obligation of Applicant to pay the regular installments required hereunder until the entire indebtedness has been paid except as otherwise provided in the Assistance Agreement.

5.Instances of Default. The Applicant agrees that the occurrence of an Instance of Default under the Assistance Agreement shall constitute an "Instance of Default" hereunder. Upon the occurrence of any Instance of Default, which remains uncured past any applicable cure period, if any, the entire indebtedness with accrued interest thereon and any other sums due under this Note, shall, at the option of the Holder, become immediately due and payable without

presentment or demand for payment, notice of non-payment, protest or any other notice or demand of any kind, all of which are expressly waived by the Applicant. Failure to exercise such option shall not constitute a waiver of the right to exercise the same in the event of any subsequent default. Upon the occurrence of any Instance of Default the interest rate shall increase to fifteen per cent per annum (15%) (the "Default Rate") and liquidated damages may be assessed in accordance with Section 4.2(C)(3) of the Assistance Agreement.

6. No Waiver. No delay or omission by Holder in exercising any rights hereunder, nor failure by the Holder to insist upon the strict performance by Applicant of any terms and provisions herein shall operate as or be deemed to be a waiver of such right, any other right hereunder, or any terms and provisions herein, and the Holder shall retain the right thereafter to insist upon strict performance by the Applicant of any and all terms and provisions of this Note or any document securing the repayment of this Note. No waiver of any right shall be effective unless in writing and signed by Holder, nor shall a waiver on one occasion be considered as a bar to, or waiver of, any such right on any future occasion.

7. Prejudgment Remedy and Other Waivers. APPLICANT ACKNOWLEDGES THAT THE LOAN EVIDENCED BY THIS NOTE IS A COMMERCIAL TRANSACTION AND WAIVES APPLICANT'S RIGHTS TO NOTICE AND HEARING, OR THE ESTABLISHMENT OF A BOND, WITH OR WITHOUT SURETY, UNDER CHAPTER 903a OF THE CONNECTICUT GENERAL STATUTES, OR AS OTHERWISE ALLOWED BY ANY STATE OR FEDERAL LAW WITH RESPECT TO ANY PREJUDGMENT REMEDY WHICH HOLDER MAY DESIRE TO USE, AND FURTHER WAIVES DILIGENCE, DEMAND, PRESENTMENT FOR PAYMENT, NOTICE OF NONPAYMENT, PROTEST AND NOTICE OF PROTEST, AND NOTICE OF ANY RENEWALS OR EXTENSIONS OF THIS NOTE, AND ALL RIGHTS UNDER ANY STATUTE OF LIMITATIONS. THE APPLICANT ACKNOWLEDGES THAT APPLICANT MAKES THESE WAIVERS KNOWINGLY AND VOLUNTARILY, WITHOUT DURESS AND ONLY AFTER EXTENSIVE CONSIDERATION OF THE RAMIFICATIONS OF THIS WAIVER. THE APPLICANT FURTHER ACKNOWLEDGES THAT THE LENDER HAS NOT AGREED WITH OR REPRESENTED TO APPLICANT OR ANY OTHER PARTY HERETO THAT THE PROVISIONS OF THIS PARAGRAPH WILL NOT BE FULLY ENFORCED IN ALL INSTANCES.

8.Jury Waiver. THE APPLICANT HEREBY WAIVES TRIAL BY JURY IN ANY COURT AND IN ANY SUIT, ACTION OR PROCEEDING ON ANY MATTER ARISING IN CONNECTION WITH OR IN ANY WAY RELATED TO THE FINANCING TRANSACTIONS OF WHICH THIS NOTE IS A PART AND/OR THE ENFORCEMENT OF ANY OF YOUR RIGHTS AND REMEDIES, INCLUDING WITHOUT LIMITATION, TORT CLAIMS. THE APPLICANT ACKNOWLEDGES THAT APPLICANT MAKES THIS WAIVER KNOWINGLY AND VOLUNTARILY, WITHOUT DURESS AND ONLY AFTER EXTENSIVE CONSIDERATION OF THE RAMIFICATIONS OF THIS WAIVER. THE APPLICANT FURTHER ACKNOWLEDGES THAT THE LENDER HAS NOT AGREED WITH OR

REPRESENTED TO APPLICANT OR ANY OTHER PARTY HERETO THAT THE PROVISIONS OF THIS PARAGRAPH WILL NOT BE FULLY ENFORCED IN ALL INSTANCES.

9. Miscellaneous. The provisions of this Note shall be binding upon the Applicant, its successors and assigns and shall inure to the benefit of Holder, its successors and assigns. If any provision of this Note shall, to any extent, be held invalid or unenforceable, then only such provision shall be deemed ineffective and the remainder of this Note shall not be affected. This Note shall be governed by and construed in accordance with the laws of the State of Connecticut (but not its conflicts of law provisions).

10. Security. This Note is secured by a Security Agreement and Patent Security Agreement between Applicant and the State.

VERMILLION, INC.

By: /s/ Valerie B. Palmieri

Valerie B. Palmieri

Its President and CEO

Duly Authorized

Dated: April 3, 2020

Exhibit 4.5

AMENDED AND RESTATED PROMISSORY NOTE #2

$2,000,000.00 April 3, 2020

Trumbull, Connecticut

FOR VALUE RECEIVED, the undersigned, **VERMILLION, INC.,** a Delaware corporation authorized to conduct business in the State of Connecticut, with an office and principal place of business located at 12117 Bee Caves Road, Building III, Suite 100, Austin, Texas 78738 (the "Applicant"), promises to pay to the order of the STATE OF CONNECTICUT, acting by and through its DEPARTMENT OF ECONOMIC AND COMMUNITY DEVELOPMENT ("State"), at its office at 505 Hudson Street, Hartford, Connecticut 06106 or at such other place as the holder hereof (including State, hereinafter referred to as "Holder") may designate, the sum of up to TWO MILLION 00/100 DOLLARS ($**2,000,000.00**) or such lesser amount as may be due and payable to State under the terms and conditions of that certain Assistance Agreement dated March 22, 2016, as amended by First Amendment to Assistance Agreement dated March 7, 2018 and as further amended by Second Amendment to Assistance Agreement dated as of even date hereof by and between Applicant and State (collectively, the "Assistance Agreement"), the terms of which are incorporated by reference herein, together with interest on the unpaid balance of this Note at the rate set forth in Section 2(a) hereof, which interest shall be computed and payable as set forth therein, together with all taxes levied or assessed on this Note or the debt evidenced hereby against the Holder, and together with all reasonable costs, expenses and reasonable attorneys' and other reasonable professionals' fees incurred in any action to collect and/or enforce this Note or to enforce, protect, preserve, defend, realize upon or foreclose any security agreement, or other agreement securing or relating to this Note, including without limitation, all reasonable costs and expenses incurred to enforce, protect, preserve, defend or sustain the lien of said security agreement, or other agreement or in any litigation or controversy arising from or connected in any manner with said security agreement, or other agreement, or this Note. Applicant further agrees to pay all reasonable costs, expenses and reasonable attorneys' and other reasonable professionals' fees incurred by Holder in connection with any "workout" or default resolution negotiations involving legal counsel or other professionals and further in connection with any re-negotiation or restructuring of the indebtedness evidenced by this Note. Any such costs, expenses and/or fees remaining unpaid after demand therefor, may, at the discretion of the Holder, be added to the principal amount of the indebtedness evidenced by this Note.

All capitalized terms not otherwise defined herein shall have the meanings ascribed to such terms in the Assistance Agreement.

This Note has been executed and delivered subject to the following terms and conditions:

1. Lawful Interest. Notwithstanding any provisions of this Note, it is the understanding and agreement of the Applicant and Holder that the maximum rate of interest to be paid by Applicant to Holder shall not exceed the highest or the maximum rate of interest permissible to be charged under the laws of the State of Connecticut. Any amounts paid in excess of such rate shall be considered to have been payments in reduction of principal.

2. Payments of Principal and Interest.

(a) The principal amount of this Note shall bear interest at a rate of two percent (2%) per annum (the "Loan Interest Rate") commencing on the date on which the One Million Dollar ($1,000,000.00) advance pursuant to Section 1.2 B of the Second Amendment to Assistance Agreement is funded (the "Advancement Date"). Commencing on the first day of the second month following the Advancement Date and on the first day of each month thereafter, Applicant shall make interest payments only. Commencing on March 1, 2023, and continuing on the same day of each and every month thereafter until the date which is ten (10) years from the first day of the month following the Advancement Date (the "Maturity Date"), and so long as no Instance of Default shall have occurred and remains uncured past any applicable cure period, principal and interest under this Note shall be payable in equal monthly installments in such a manner as to fully amortize the Loan over the remaining term of this Note.

(b) The entire indebtedness under this Note, including, all outstanding principal (including amounts not forgiven or repaid), accrued and unpaid interest, if any, and any other obligations due hereunder or under the Assistance Agreement, shall be due and payable in full on the Maturity Date.

(c) Payments in respect of this Note shall be made payable to "The State of Connecticut, Department of Economic and Community Development".

(d) The principal amount of this Note is subject to a Forgiveness Credit and a Job Penalty in accordance with the provisions of Section 2.17 of the Assistance Agreement.

(e) In the event that a Job Penalty is assessed or a Forgiveness Credit is given in accordance with Section 2.17 of the Assistance Agreement, monthly payment of principal and interest shall be adjusted in accordance with said sections.

1. Late Charge. In the event Applicant fails to pay any installment of principal and/or interest within fifteen (15) days of the date when said amount was due and payable, without in any way affecting the Holder's right to accelerate this Note, a late charge equal to five percent

(5.00%) of such late payment shall, at the option of Holder, be assessed against Applicant and be due upon demand by the Holder.

4. Prepayments. The Applicant may prepay principal of this Note, in whole or in part, at any time without penalty or premium. Any and all prepayments shall be applied first to accrued and unpaid interest and then to unpaid principal in the inverse order of maturity, and shall not affect the obligation of Applicant to pay the regular installments required hereunder until the entire indebtedness has been paid except as otherwise provided in the Assistance Agreement.

5. Instances of Default. The Applicant agrees that the occurrence of an Instance of Default under the Assistance Agreement shall constitute an "Instance of Default" hereunder. Upon the occurrence of any Instance of Default, which remains uncured past any applicable cure period, if any, the entire indebtedness with accrued interest thereon and any other sums due under this Note, shall, at the option of the Holder, become immediately due and payable without presentment or demand for payment, notice of non-payment, protest or any other notice or demand of any kind, all of which are expressly waived by the Applicant. Failure to exercise such option shall not constitute a waiver of the right to exercise the same in the event of any subsequent default. Upon the occurrence of any Instance of Default the interest rate shall increase to fifteen per cent per annum (15%) (the "Default Rate") and liquidated damages may be assessed in accordance with Section 4.2(C)(3) of the Assistance Agreement.

6. No Waiver. No delay or omission by Holder in exercising any rights hereunder, nor failure by the Holder to insist upon the strict performance by Applicant of any terms and provisions herein shall operate as or be deemed to be a waiver of such right, any other right hereunder, or any terms and provisions herein, and the Holder shall retain the right thereafter to insist upon strict performance by the Applicant of any and all terms and provisions of this Note or any document securing the repayment of this Note. No waiver of any right shall be effective unless in writing and signed by Holder, nor shall a waiver on one occasion be considered as a bar to, or waiver of, any such right on any future occasion.

7. Prejudgment Remedy and Other Waivers. APPLICANT ACKNOWLEDGES THAT THE LOAN EVIDENCED BY THIS NOTE IS A COMMERCIAL TRANSACTION AND WAIVES APPLICANT'S RIGHTS TO NOTICE AND HEARING, OR THE ESTABLISHMENT OF A BOND, WITH OR WITHOUT SURETY, UNDER CHAPTER 903a OF THE CONNECTICUT GENERAL STATUTES, OR AS OTHERWISE ALLOWED BY ANY STATE OR FEDERAL LAW WITH RESPECT TO ANY PREJUDGMENT REMEDY WHICH HOLDER MAY DESIRE TO USE, AND FURTHER WAIVES DILIGENCE, DEMAND, PRESENTMENT FOR PAYMENT, NOTICE OF NONPAYMENT, PROTEST AND NOTICE OF PROTEST, AND NOTICE OF ANY RENEWALS OR EXTENSIONS OF THIS NOTE, AND ALL RIGHTS UNDER ANY STATUTE OF LIMITATIONS. THE APPLICANT ACKNOWLEDGES THAT APPLICANT MAKES THESE WAIVERS KNOWINGLY AND VOLUNTARILY, WITHOUT DURESS AND ONLY AFTER EXTENSIVE CONSIDERATION OF THE RAMIFICATIONS OF THIS WAIVER. THE APPLICANT FURTHER ACKNOWLEDGES THAT THE LENDER HAS NOT AGREED WITH OR REPRESENTED TO APPLICANT OR ANY OTHER PARTY HERETO THAT THE PROVISIONS OF THIS PARAGRAPH WILL NOT BE FULLY ENFORCED IN ALL INSTANCES.

8. Jury Waiver. THE APPLICANT HEREBY WAIVES TRIAL BY JURY IN ANY COURT AND IN ANY SUIT, ACTION OR PROCEEDING ON ANY MATTER ARISING IN CONNECTION WITH OR IN ANY WAY RELATED TO THE FINANCING TRANSACTIONS OF WHICH THIS NOTE IS A PART AND/OR THE ENFORCEMENT OF ANY OF YOUR RIGHTS AND REMEDIES, INCLUDING WITHOUT LIMITATION, TORT CLAIMS. THE APPLICANT ACKNOWLEDGES THAT APPLICANT MAKES THIS WAIVER KNOWINGLY AND VOLUNTARILY, WITHOUT DURESS AND ONLY AFTER EXTENSIVE CONSIDERATION OF THE RAMIFICATIONS OF THIS WAIVER. THE APPLICANT FURTHER ACKNOWLEDGES THAT THE LENDER HAS NOT AGREED WITH OR REPRESENTED TO APPLICANT OR ANY OTHER PARTY HERETO THAT THE PROVISIONS OF THIS PARAGRAPH WILL NOT BE FULLY ENFORCED IN ALL INSTANCES.

9. Miscellaneous. The provisions of this Note shall be binding upon the Applicant, its successors and assigns and shall inure to the benefit of Holder, its successors and assigns. If any provision of this Note shall, to any extent, be held invalid or unenforceable, then only such provision shall be deemed ineffective and the remainder of this Note shall not be affected. This Note shall be governed by and construed in accordance with the laws of the State of Connecticut (but not its conflicts of law provisions).

10. Security. This Note is secured by a Security Agreement and Patent Security Agreement between Applicant and the State.

VERMILLION, INC.

By: /s/ Valerie B. Palmieri

Valerie B. Palmieri

Its President and CEO

Duly Authorized

Dated: April 3, 2020

SECOND AMENDMENT
TO
ASSISTANCE AGREEMENT BY AND BETWEEN
THE STATE OF CONNECTICUT
ACTING BY THE DEPARTMENT OF ECONOMIC AND COMMUNITY DEVELOPMENT
AND
VERMILLION, INC.

Re: Vermillion Relocation Project

THIS SECOND AMENDMENT to the Assistance Agreement dated March 22, 2016 (the "Assistance Agreement") is made and entered into by and between the **STATE OF CONNECTICUT** (hereinafter the "State"), acting herein by David Lehman, its Commissioner of Economic and Community Development (hereinafter "Commissioner"), and the **VERMILLION, INC.**, a Delaware corporation (hereinafter the "Applicant"), acting herein by Valerie B. Palmieri, its duly authorized President and Chief Executive Officer.

All capitalized terms not otherwise defined herein have the meanings ascribed to them in the Assistance Agreement.

W I T N E S S E T H:

WHEREAS, the State and the Applicant entered into the Assistance Agreement whereby the State agreed to provide financial assistance to the Applicant for the Project in the form of a loan in the amount not to exceed FOUR MILLION AND NO/100 DOLLARS ($**4,000,000.00**) (hereinafter the "Loan"); and

WHEREAS, the Applicant and the State entered into a First Amendment to Assistance Agreement dated March 7, 2018 (First Amendment") to amend Section 2.17 A of the Assistance Agreement; and

WHEREAS, the Applicant has requested a modification to the Assistance Agreement to change the manner of disbursement of the Loan, as well to amend the Employment Obligation and the Forgiveness Credit as provided in the Assistance Agreement as modified by the First Amendment;

NOW, THEREFORE, in consideration of the mutual promises of the parties hereto, and of the mutual benefits to be gained by the performance thereof, the State and the Applicant hereby agree to amend the Assistance Agreement as follows:

1. Section 1.2 of the Assistance agreement is hereby deleted in its entirety and the following substituted in lieu thereof:

1.2 Disbursement of the Loan:

A. The first $2,000,000.00 of the Loan shall be disbursed (i) upon the closing of this financial assistance; (ii) whenever the Applicants shall have established its operations in and taken occupancy of its Trumbull, Connecticut location at 35 Nutmeg Drive; and (iii) upon the Applicant providing evidence on its balance sheet showing at least $18,800,000.00 of additional capital investment.

B. Thereafter, $1,000,000.00 of the Loan shall be disbursed (i) after Commissioner's approval per Section 1.1 above, (ii) after the Applicant shall have received clearance from the Food and Drug Administration

(FDA) for OVA 2 and (iii) upon verification by the State of the creation of 25 full time jobs prior to the Target Date referred to in Section 2.17 infra.

C. The last remaining $1,000,000.00 balance of the Loan shall be disbursed after subsection B above is satisfied and the Applicant shall have achieved gross consolidated revenue of $5,000,000.00 for any trailing twelve (12) month period.

2. Section 2.17 of the Assistance Agreement as modified by the First Amendment is hereby deleted in its entirety and the following is hereby substituted in its place:

2.17 Job Creation and Retention; Job Audit; Penalty; Forgiveness Credit.
*(A) The Applicant will create and retain twenty five (25) full-time employment positions with an average annual salary of $85,000.00 in Connecticut on or before December 31, 2020 (the "**Target Date**", and shall maintain such positions for twenty-four (24) consecutive months thereafter (the "**Employment Obligation**"). A full-time employment position is defined as a position that is paid for a minimum of forty (40) hours per week. The twenty-four (24) consecutive month period ending on or before the Target Date that yields the highest annual average positions will be used to determine compliance with the Employment Obligation, provided that no portion of said twenty-four (24) consecutive months may begin before the Agreement Date.*

3. Section 2.17 (D) of the Assistance Agreement is hereby deleted in its entirety and the following is hereby substituted in its place:

*(D) The Applicant may be eligible for a credit to be applied against the outstanding principal balance of the Loan (the "**Forgiveness Credit**") in accordance with the following:*

(i) If as a result of a Job Audit, the Commissioner determines that the Applicant has met its Employment Obligation and that the employment positions created and retained are at an average annual salary of not less than $80,750.00 (the "Threshold Salary") (i.e. 95% or more of the "Baseline Salary" of Eighty Five Thousand and 00/100 Dollars ($85,000.00)) the Applicant shall receive a credit in the amount of One Million and 00/100 Dollars ($1,000,000.00) which will be applied against the then outstanding principal balance of the Loan. If the Applicant shall have created and retained 40 full time positions on or before December 31, 2022 (i.e. ten (10) more than the Employment Obligation of 30 full time positions), then the Applicant shall receive an additional Forgiveness Credit of $500,000.00 for a total of $1,500,000.00. Upon application of the Forgiveness Credit, the Commissioner shall recalculate the monthly payments of principal and interest under the Amended and Restated Promissory Note #2 Note such that such monthly payments shall amortize the then remaining principal balance over the remaining term of the Amended and Restate Promissory Note #2.

(ii) Notwithstanding the foregoing, if, as a result of the Job Audit conducted in accordance with this Section 2.17, the Commissioner determines that the Applicant has met its Employment Obligation but that the average annual salary of full-time employees created and retained is less than $80,750.00, any Forgiveness Credit for which the Applicant would otherwise be eligible to receive pursuant to Section 2.17(D)(i) above shall be reduced by a number equal to the result of the following formula: (the difference between the Baseline Salary and the actual average annual salary of new full-time employees) divided by the Baseline Salary, and multiplied by the Forgiveness Credit the Applicant is otherwise eligible to receive. For Example, if the Applicant met its Employment Obligation of 25 jobs created and retained for a period of twenty-four (24) consecutive months and, based on the Job Audit, it is determined that the Company had an actual annual salary of $75,000.00 per eligible employee, then the following would be the calculation for the reduction in the Forgiveness Credit: ($85,000.00-$75,000.00)/$85,000.00 multiplied by $1,000,000.00 = $117,647.06. Therefore, the actual adjusted Forgiveness Credit would be $982,352.94 (i.e. $1,000,000.00 less $117,647.06).

4. The Note referred to in Section 1.3 of the Assistance Agreement shall be voided and replaced with (i) an Amended and Restated Promissory Note #1 (for $2,000,000.00) and (ii) an Amended and Restated Promissory Note #2, (for $2,000,000.00) copies of which are attached hereto as Exhibit 1 and Exhibit 2 respectively, and made a part hereof.

5. Applicant does hereby expressly ratify, conform and restate the grant of liens, security interests and other encumbrances in the Collateral provided as security for the Loan, as amended herein, pursuant to the Security

Agreement and Patent Security Agreement executed by the Applicant pursuant to the Assistance Agreement dated March 22, 2016.

Except as herein modified the Assistance Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto make and enter into this Agreement.

VERMILLION, INC.

By: /s/ Valerie B. Palmieri

Name: Valerie B. Palmieri

Title: President and CEO

Duly Authorized

Dated: March 24, 2020

STATE OF CONNECTICUT DEPARTMENT OF ECONOMIC AND COMMUNITY DEVELOPMENT

By: /s/ David Lehman

Name: David Lehman

Title: Commissioner

Duly Authorized

Dated: April 3, 2020

EXHIBIT 1

Amended and Restated Promissory Note #1

[Intentionally omitted.]

EXHIBIT 2

Amended and Restated Promissory Note #2

[Intentionally omitted.]

Exhibit 21.0

Vermillion, Inc. Subsidiaries

December 31, 2019

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, 333-226462 and 333-232541) of Vermillion, Inc. of our report dated April 7, 2020, 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
April 7, 2020

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, 2019 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 disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act 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: April 7, 2020

/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, 2019 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 disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act 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: April 7, 2020

/s/ Robert Beechey

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

Exhibit 32.0

Certification

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, 2019

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, 2019, (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 information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 7, 2020

/s/ Valerie B. Palmieri

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

Date: April 7, 2020

/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.