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, 2020 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

_____

Aspira Women's Health 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 III, 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	**AWH**	**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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No

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 $290,267,539 and is based upon the last sales price as quoted on The NASDAQ Capital Market as of June 30, 2020.

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 29, 2021, the registrant had 111,716,852 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, 2020.

ASPIRA WOMEN'S HEALTH INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2020

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The following are registered and unregistered trademarks and service marks of Aspira Women's Health Inc.: VERMILLION®, ASPIRA WOMEN'S HEALTH™, OVA1®, OVERA®, ASPIRA LABS®, ASPIRA IVD®, OVACALC®, ASPIRA GENETIX℠, OVA1PLUS®, OVASIGHT™, ENDOCHECK™, OVAINHERIT™, ASPIRA SYNERGY℠, and OVA360™.

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 Annual Report on Form 10-K is filed with the Securities and Exchange Commission (the "SEC"), and, except as required by law, Aspira Women's Health Inc. ("Aspira" 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 include, without limitation:

- expectations relating to the Paycheck Protection Program loan (the "PPP" Loan);
- projections or expectations regarding our future test volumes, revenue, cost of revenue, operating expenses, research and development expenses, gross profit margin, 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, including additional pelvic disease conditions such as endometriosis;
- our planned business strategy and strategic business drivers and the anticipated effects thereof;
- plans to commercialize OVA1, OVERA, OVA1plus, Aspira GenetiX, OVASight, EndoCheck and OVAInherit on a global level;
- plans to develop new algorithms, molecular diagnostic tests, products and tools and otherwise expand our product offerings, including plans to develop a product using genetics, proteins and other modalities to assess the risk of developing cancer when carrying a pathogenic variant associated with hereditary breast and ovarian cancer that is difficult to detect through a diagnostic test;
- 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;
- anticipated efficacy of our products, product development activities and product innovations, including our ability to improve sensitivity and specificity over traditional diagnostic biomarkers;
- expected competition in the markets in which we compete;
- plans with respect to ASPiRA LABS, including plans to expand ASPiRA LABS' testing capabilities;
- plans to add a genetics laboratory to our Connecticut office;
- expectations regarding future services provided by Quest Diagnostics Incorporated;
- plans to develop informatics products and develop and perform laboratory developed tests ("LDTs");
- plans to develop an ethnicity-specific pelvic mass risk assessment;
- expectations regarding existing and future collaborations and partnerships for our products, including plans to enter into decentralized arrangements for our Aspira Synergy product;
- plans regarding future publications;

- our ability to continue to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests within the United States and internationally, as applicable;
- our continued ability to expand and protect our intellectual property portfolio;
- anticipated liquidity, capital requirements and future losses;
- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations;
- expectations regarding the results of our clinical utility studies and our ability to recruit patients to participate in such studies;
- our ability to use our net operating loss carryforwards and 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 reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans;
- plans to use AbbVie Inc. serum samples in EndoCheck product validation studies;
- expectations regarding the wind down of our ASPiRA IVD, Inc. subsidiary and future service revenue;
- expectations in leveraging telehealth, including for the development of a process for patients to access Aspira GenetiX testing directly; and
- expectations regarding the impacts resulting from or attributable to the COVID-19 pandemic and actions taken to contain it.

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 impacts resulting from or relating to the COVID-19 pandemic and actions taken to contain it; expectations regarding the forgiveness of the PPP loan, anticipated use of capital and its effects; our ability to increase the volume of our product sales; failures by third-party payers to reimburse for our products and services or changes to reimbursement rates; our ability to continue developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform LDTs; our ability to comply with Food and Drug Administration ("FDA") regulations that relate to our products and to obtain any FDA clearance or approval required to develop and commercialize medical devices; 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; or our suppliers' ability to comply with FDA requirements for production, marketing and post-market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; in the event that we succeed in commercializing our products outside the United States, the political, economic and other conditions affecting other countries; 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 use our net operating loss carryforwards; our ability to use intellectual property directed to diagnose biomarkers; our ability to successfully defend our proprietary technology against third parties; our ability to obtain licenses in the event a third party successfully asserts proprietary rights; the liquidity and trading volume of our common stock; the concentration of ownership of our common stock; our ability to retain key employees; our ability to secure additional capital on acceptable terms to execute our business plan; business interruptions; the effectiveness and availability of our information systems; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; future litigation against us, including infringement of intellectual property and product liability exposure; and additional costs that may be required to make further improvements to our manufacturing operations.

ITEM 1. BUSINESS

Company Overview

Corporate Vision: Our core mission is 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 ovarian 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.

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 determine risk, detect disease, and help guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, to assist in monitoring patients, to understand genetic predisposition and to help guide clinical management. A distinctive feature of our approach is the combination of multi-modal diagnostics and data. Our goal is to combine multiple biomarkers, additional modalities and diagnostics, clinical risk factors and patient data into a single, reportable index score that has a higher diagnostic accuracy than any of its individual constituents, some of which are the current standard of care. We are measuring protein levels that are associated with inflammation and nutrition in a response to an invasive mass in the pelvic area. We concentrate our development on 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 and prognosis through collaborations with leading academic and research institutions.

Scientific Bases for Our Products:

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, or is present in an altered form, 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. Aspira and its collaborators are considered experts in these areas and, in the case of OVA1 and OVERA, presented both the clinical validation and error modeling needed in order to gain pre-market authorization from the Food and Drug Administration. In the case of OVA1, FDA granted a "de novo" request for classification of an ovarian adnexal mass assessment score test system, a type of in vitro diagnostic device; in the case of OVERA (previously OVA1 Next Generation) FDA granted a 510(k) clearance.

Science of Genomic Targets: Our focus on genomic targets allows us to address the drivers of the disease and develop diagnostic tests that detects genetic drivers at early stages to improve survival rates, as well as detect the drivers of disease recurrence. In clinical genetic testing there are two approaches in utilizing genomic targets of disease. The first approach, offered by our Aspira GenetiX testing platform, is to utilize germline testing to identify well-established and highly prevalent genes associated with gynecological cancers that can help in understanding a women's life-time risk in developing gynecological cancer. The second approach, which is our new focus, is to utilize transcriptomics and somatic genomic targets to classify the progression of ovarian cancer, which is currently diagnosed by histopathology. Our research and development and innovation team is actively utilizing the latter approach to identify the key drivers of gynecological cancer that can then be detected in the blood by measuring cell-tumor DNA (ctDNA) from the developing tumor and stratifying the risk of ovarian cancer early.

Science of Proteogenomics: We are embracing the era of precision medicine, which in the case of disease detection and prevention means accounting for each individual's variability in genes, environment and lifestyle in order to refine disease detection. Proteogenomics accounts for the combination of proteomic data, or the measurement of proteins in the blood to assess cancerous pathologies and genomic data, or the measurement of the molecular basis of the cancer (i.e. the driver), as measuring the two in combination strengthens the ability to diagnose cancer early in the blood. We plan to build a proteogenomic approach, which will combine our already established protein biomarkers of ovarian cancer (i.e. OVA1, OVERA, OVA1plus) with genomic targets that characterizes the drivers of mutation of ovarian cancer. This proteogenomic approach should enable us to develop and validate a novel prognostic and diagnostic test for ovarian cancer, thereby allowing for specific targeted therapies. We expect this will be our new foundational model of all new test development moving forward.

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 OVA1's high sensitivity while improving specificity; (3) OVA1plus, a reflex offering which uses OVA1 primarily and OVERA as a confirmation for OVA1 intermediate range results. This reflex leverages the strengths of OVA1's Multivariate Index Assay ("MIA") sensitivity and OVERA's (MIA2G) specificity and as a result reduces false elevations by over 40%. (4) Aspira GenetiX, a genetic test for gynecologic cancer risk, with a core focus on female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers, and (5) Aspira Synergy, our new decentralized platform and cloud service technology, which we plan to house our algorithms for decentralized global access. We plan to make OVA1, OVERA, OVA1plus and Aspira GenetiX available through Aspira Synergy. Our OVA1 algorithm received FDA de novo classification in September 2009, and our OVERA algorithm received FDA 501(k) clearance in March 2016. OVA1 and OVERA each use the Roche cobas 4000, 6000 and 8000 platforms for analysis of proteins. Through December 31, 2020, our product and related services revenue has been limited to revenue generated by sales of OVA1, OVA1plus and Aspira GenetiX. In 2021 we plan to begin entering into decentralized arrangements with large healthcare networks and large practices for our Aspira Synergy product.

We are developing three additional products and related services, including two diagnostic algorithms, OVASight (previously OVANex) and EndoCheck, and a high-risk diagnostic algorithm, OVAInherit, for patients with or without a pelvic mass who are genetically predisposed to ovarian cancer. These products may be launched as LDTs or FDA-cleared tests.

- OVASight is validated to confirm risk of malignancy for women with an indeterminate mass that includes not only biomarkers, but also other clinical risk factors, and potentially other diagnostics and patient history data to increase predictive value. OVASight is our third-generation risk of malignancy for ovarian cancer test and focuses on women who present with an indeterminate mass with a very low-risk of cancer. In this group, women with a low-risk have the potential to be sequentially monitored to a finalized classification of low-risk or high-risk. This is intended for women who are not planned for surgery.
- EndoCheck will be designed as a blood test to aid in diagnosis of endometriosis and is to be used in conjunction with other non-surgical modalities. Current detection methods for endometriosis require a surgical biopsy, while EndoCheck is intended to address this large patient population using a non-surgical solution with both the sensitivity and specificity equal to or greater than surgical biopsy. We submitted an application to the FDA under its Breakthrough Devices Program in the first quarter of 2021, and expect to have a dialogue with the FDA in the second quarter of 2021.
- OVAInherit will be designed as a high-risk diagnostic tool, intended for those patients with or without a pelvic mass who are genetically predisposed to

gynecologic cancer. It will use genetics, proteins and other modalities to assess the risk of gynecologic cancers early without visible presence of cancer via traditional ultrasound methodologies. Our related trial, OVA360, has launched and will be focused on developing a diagnostic test for the early detection of ovarian cancer.

We ultimately plan to commercialize each of OVA1, OVERA, OVA1plus, Aspira GenetiX, OVASight, EndoCheck and OVAInherit on a global level. We currently hold CE marks for OVA1 and OVERA. In addition, each of OVA1 and OVERA and the combination OVA1plus will be offered on our global testing platform, which allows both tests to be deployed worldwide.

Outside of the United States, we have studies in process to validate OVERA and OVA1 in specific populations. This includes 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 our decentralized technology, Aspira Synergy, for OVERA specimen testing.

We own and operate Aspira Labs, Inc. ("ASPiRA LABS"), based in Austin, Texas, a Clinical Chemistry and Endocrinology Laboratory accredited by the College of American Pathologists, 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 risk assessment 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 Clinical Laboratory Improvements Amendments of 1988 ("CLIA") Certificate of Accreditation and a state laboratory license in California, Maryland, New York, Pennsylvania and Rhode Island. This allows the lab test OVA1 and OVERA to be performed on a national basis. The Centers for Medicare & Medicaid Services ("CMS") issued a supplier number to ASPiRA LABS in 2015.

We had previously planned to offer COVID-19 antibody and antigen testing in connection with our pre-surgical test offering, as physicians had requested these tests to solve for shortages of testing on the local level. In the fourth quarter of 2020, we decided not to proceed with this offering as such tests are now readily available to our physician partners at the local, regional level.

The Company has historically 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 was a specialized, CLIA certified, laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. The Company has discontinued pursuing contracts for ASPiRA IVD and its contractual commitments were largely concluded in the fourth quarter of 2019.

Core Products

About OVA1 and OVERA: Our initial product, OVA1, is a blood test designed to be used in conjunction with a physician's clinical assessment (which includes imaging) of a woman with a pelvic mass, to identify women who are at high-risk of having a malignant ovarian tumor prior to planned surgery when the physician's independent clinical and radiological evaluation does not indicate malignancy. The FDA issued a de novo authorization for OVA1 in September 2009, and we commercially launched OVA1 in March 2010. In March 2016, we received FDA 510(k) clearance for a second-generation biomarker panel known as OVA1 Next Generation, which we call OVERA and which is intended to maintain OVA1's high sensitivity while improving specificity.

In November 2016, the American College of Obstetricians and Gynecologists ("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 is a reflex test performed for those OVA1 test results that are in the intermediate risk range. For all OVA1 test results in this intermediate risk range, OVERA is performed to stratify a patient's risk of malignancy. This is designed to improve diagnostic accuracy by increasing specificity which reduces false positive rate by 40%. OVA1plus also helps drive earlier detection, which in turn

may lower overall healthcare costs and reduce inefficiencies in the care pathway. We expect OVA1plus to be available through our decentralized platform structure, Aspira Synergy. This will allow other facilities, including hospital networks and large doctor practices, to perform OVA1plus locally, upload the clinical data and receive the OVA1plus score, enabling point of care testing, increased reach and worldwide access to our OVA1plus technology.

About Aspira GenetiX: In June 2019, we launched Aspira GenetiX, which is a genetic test for gynecologic cancer risk, with a core focus on female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers. Aspira GenetiX's initial offering is designed to detect hereditary breast and gynecological cancer syndromes and test for genetic carriers of autosomal recessive and X-linked diseases. Women who test positive for variants of such highly-prevalent genes associated with hereditary risk have an elevated life-time risk of developing cancers (more than 1.3% higher than the general population's risk for ovarian cancer). Aspira GenetiX complements OVA1plus and is sold at the same call point. Using Aspira GenetiX in combination with OVA1plus offers physicians a comprehensive personalized risk assessment for ovarian cancer. As of January 2021, our Aspira GenetiX report includes enriched literature data and approved National Comprehensive Cancer Network (NCCN) clinical management guidelines for those women who present with a positive genetic finding. This allows immediate clinical management access to the clinician so they may counsel their patient in a timely manner.

About Aspira Synergy: In January 2021, we completed the validation of our new decentralized platform and cloud service technology, now branded as Aspira Synergy. Aspira Synergy is an en-suite, cloud-based technology transfer solution that provides an end-to-end platform (sample collection to customized report) for clinical laboratories to internalize testing of our products. Within Aspira Synergy we will launch two sub products, Aspira Synergy Liquid Biopsy for our OVA1plus service offering, consisting of the OVA1 and OVERA tests, and Aspira Synergy Genetics for genetic testing. The Aspira Synergy Liquid Biopsy product, planned to launch in 2021, will allow other facilities to perform OVA1plus locally and upload clinical data and receive the OVA1plus score, enabling increased reach and access. The Aspira Synergy Genetics product is a fully validated Next-Generation Sequencing assay which is offered to laboratories to validate and run locally as their own LDT. Aspira Synergy Genetics, which completed validation in January 2021, is comprised of a custom-built technology which leverages a novel artificial intelligence-based bioinformatics pipeline that has been customized specifically for the proprietary Aspira genetics chemistry, resulting in reduced workflows and redundancies typically associated with internalizing genetics. Aspira Synergy Genetics is fully automated, providing limited wet lab and sample analysis time, allowing clients to implement and run genetic testing at scale and with minimal cost, time and labor at accelerated turn-around times. This year we expect to be granted a CLIA Certificate of Accreditation for our laboratory at our Connecticut office, which would enable us to house a molecular research genetics laboratory to support our Aspira Synergy platform, among others, as well as additional tests that include genomic technology. We expect Aspira Synergy will expand our breadth and reach of access for all Aspira products, as every commercialized product as well pipeline innovations, will be blended into our Aspira Synergy platform.

Product Pipeline

About OVASight: The OVASight blood test, previously referred to as OVANex, is designed to support detecting the risk of malignancy in women with an indeterminate mass by using the test to first confirm a benign mass and potentially monitor the mass, in conjunction with ultrasounds, and then to confirm a risk of malignancy and lastly to help assess clinical management next steps. The OVASight technology will be validated for application in three separate cohorts of women. The first cohort is patients with a pelvic mass and symptoms. The second cohort is women whose pelvic mass is found incidentally and are asymptomatic, and that are also not scheduled for surgery. The third cohort is women with or without a pelvic mass that are genetically predisposed to develop ovarian cancer. Validation in this overall patient population will be supported by our longitudinal prospective clinical study launched in 2020. The OVASight test will be launched initially as an LDT, but we may choose in the future to submit an FDA marketing application for the test. The OVASight test is expected to have a high sensitivity and specificity as well as a high negative predictive value of greater than 99%, which will allow physicians to serially monitor women with a mass to delay or avoid unnecessary surgery. A serial monitoring solution, which involves testing each patient two to four times a year in conjunction with an ultrasound, presents a new and potentially large market opportunity for us. We expect Phase I of OVASight to be commercially available in the fourth quarter of 2021.

About EndoCheck: The EndoCheck blood test is designed to be an aid in the diagnosis and detection of endometriosis We submitted an application to the FDA under its Breakthrough Devices Program in the first quarter of 2021, and expect to have a dialogue with the FDA in the second quarter of 2021. This test is expected to have a high sensitivity and specificity as compared to laparoscopic surgical assessment. The current Breakthrough Devices Program submission includes data from several retrospective studies, including specimens from our own internal databank of benign cancers with confirmed histopathology of endometriosis or endometrioma, as well as diagnosed intended use populations with moderate to severe pain from both the AbbVie Elagolix trial and ENDOmarker study that was designed by the NICHD Reproductive Medicine Network (RMN). If a prospective study is not required to support marketing authorization, we expect to shorten our timeline and bring the product to

market earlier. If a prospective study is required to support marketing authorization, we expect to develop and validate the test in 2022 and commercially launch in the first half of 2023 as a CE-marked, FDA-cleared product (subject to the receipt of requisite regulatory authorizations).

About OVAInherit: The OVAInherit blood test will be a high-risk diagnostic test for those patients who are genetically predisposed to ovarian cancer. Studies have shown that in the general population 1 in 400 women have a prevalence of high-risk gene *BRCA1/2*, while among people of Ashkenazi Jewish descent 1 in 40 have a combined frequency for three *BRCA1/2* variants. This multi-modal solution will include genetics, proteins and other modalities to deliver a personalized risk assessment of ovarian cancer. We plan to pursue FDA 510(k) clearance and a CE Mark for this product. In the second half of 2020 we began a clinical study for our OVAInherit product, which we refer to as OVA360. There is no definite timeline for the OVAInherit launch at this time.

Strategy: We are focused on execution of the following core strategic business drivers in women's pelvic mass assessment, starting with ovarian cancer diagnostics, and specialized laboratory services to build long-term value for our investors:

- Maximizing the existing OVA1 opportunity in the United States by actively pursuing payer coverage and commercialization of OVA1;
- 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 women's health diseases with a focus on pelvic disease conditions such as pelvic mass monitoring and endometriosis by adding additional gynecologic bio-analytic solutions involving biomarkers, genetics, other modalities (e.g., imaging), clinical risk factors and patient data to aid diagnosis and risk stratification of women presenting with a pelvic mass;
- Coupling our OVA1 products with an individual's hereditary genetic risk to refine ovarian cancer risk assessment for the high-risk populations; and
- Expanding distribution avenues to super groups and health systems through our de-centralized testing platform, Aspira Synergy.

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

In 2020, we did a study on low-risk Multivariate Index Assay ("MIA") scores, physician referral and surgical choices in women with adnexal masses. This was a retrospective chart study showing that a high proportion of low-risk OVA1 patients were not referred to a gynecologic oncologist prior to surgery, indicating gynecologists may use MIA OVA1 along with clinical and radiographic findings to retain patients for their care. See our 2019 Annual Report on Form 10-K for a list of peer reviewed publications or articles published by outside parties regarding our technology.

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 2020, Allied Market Research, a market research and business consulting partnership, published a study which forecasts the global IVD market to reach $91.1 billion by 2027, growing at a compound annual growth rate of 4.8% from 2019 to 2027. 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 21,000 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 (stage 1), patients have up to a 92.6% 5-year survival rate following surgery and/or chemotherapy. 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 22.5%.

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. Invasive masses have a disease outside the pelvic mass and need to go to chemotherapy treatment immediately followed by surgical removal. The goal is to catch the mass early before it becomes an invasive 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 for the monitoring for recurrence of ovarian cancer only, 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, Incorporated ("Quest Diagnostics"). Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Aspira's wholly-owned subsidiary, ASPiRA LABS. Pursuant to this agreement as subsequently amended, Quest Diagnostics has continued to provide blood draw and logistics support by transporting specimens from its clients 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.

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 the combinations of biomarkers with genomics that can be developed into diagnostic assays. We have done this predominantly through collaborations we have established with academic institutions such as the Johns Hopkins University School of Medicine, and the University of Texas, M.D. Anderson Cancer Center as well as through genetic testing providers such as Baylor Genetics. 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.

Two of the new genomic targets currently under consideration for validation are (a) circulating DNA mutations from cancer genes; and (b) 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, Aspira 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 13,557 OVA1 tests were performed in 2020 compared to 12,898, in 2019, with the increase being attributed to expanded commercial efforts. In 2020, 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. Due to OVA1 tests being 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, 2020, Aspira'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.

The Company does not expect to have any significant service revenue going forward, as we stopped performing ASPiRA IVD trial services for third-party customers in the fourth quarter of 2019. For 2020, the Company's service revenue was limited to the fulfillment of one legacy IVD contract.

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 2022.

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 through 2022.

In 2020, we announced 7 new contractual arrangements which brought the total number of covered lives to approximately 173 million as of December 31, 2020.

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, Abbott Laboratories, Exact Sciences (Thrive), Grail, Anixa, Angle and InterVenn 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 federally registered trademarks and service marks as well as federally pending trademark and service mark applications for our product and service offerings 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 19 issued United States patents, 8 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 FD&C Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of our products. The FD&C Act requires that medical devices introduced to the United States market, unless exempted by regulation, be authorized by FDA pursuant to either the premarket notification pathway, known as 510(k) clearance, the de novo classification pathway, or the premarket approval (PMA) pathway. OVA1 was authorized by the FDA in September 2009 under the *de novo* classification pathway. OVA1 was the first FDA-authorized 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.

ASPiRA LABS and any laboratory customers using our products for clinical use in the United States are subject to regulation 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, moderate complexity and high complexity - and the standards applicable to a clinical laboratory depend on the level of the tests it performs. This year we expect to be granted a CLIA Certificate of Accreditation for our laboratory at our Connecticut office, which would enable us to house a molecular research genetics laboratory to support each of our OVASight, EndoCheck, OVAInherit and Aspira Synergy platforms, as well as additional tests that include genomic technology.

FDA Regulation of Cleared Tests. Once granted, a 510(k) clearance or PMA 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 comply with the FDA's QSRs, which require that we adhere to a quality policy and that our devices are manufactured and records be maintained in a prescribed manner with respect to manufacturing, testing and control activities. We are subject to other record-keeping and reporting requirements. Additionally, we are subject to inspection by the FDA. 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, under the FD&C Act, the FDA may require post-market surveillance of medical devices as a condition of

granting marketing authorization. Non-compliance with FDA requirements can result in, among other things, fines, injunctions, civil monetary penalties, seizures, recalls, prosecution and total or partial suspension of production.

With respect to OVA1, the FDA required us to perform post-market surveillance to gather additional data regarding test performance. This study has been completed.

In addition, the medical device reporting regulation requires that we provide information to the FDA whenever we receive information that 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, Aspira 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, 2020, we had 68 full-time employees and 69 total employees. We generally engage independent contractors on a part-time basis 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 Business Conduct and Ethics for employees, agents, contractors, consultants, officers and members of our board of directors by posting the policy on our website, www.aspirawh.com. We will disclose on our website any waivers of, or amendments to, our Code of Business Conduct and 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 III, Suite 100, Austin, Texas 78738, and our telephone number is (512) 519-0400. We maintain a website at www.aspirawh.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.aspirawh.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
Aspira Women's Health Inc.
12117 Bee Caves Road, Building III, 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 THE COVID-19 PANDEMIC

The novel coronavirus outbreak and the COVID-19 pandemic have adversely impacted, and are expected to further adversely impact, our business, results of operations and financial condition, and such future adverse impact may be material. In addition, other health epidemics, outbreaks or pandemics may adversely affect our business, results of operations and financial condition.

We face risks related to health epidemics and other outbreaks, including the global outbreak of the novel coronavirus and the disease caused by it, COVID-19. Beginning in March 2020, the COVID-19 pandemic and actions taken to contain it have led to travel restrictions, stay-at-home mandates and limitations on access to hospitals and other medical facilities. As a result, our test volumes decreased for a period of time but have recovered, as fewer new patients were tested particularly from March to August 2020 and existing patients extended planned testing schedules. In addition, travel restrictions and stay-at-home mandates have limited recruitment of individuals to participate in our research studies, which has caused delays in our product development timelines. Our salespeople have been limited in their ability to make in-person sales calls. Although we have adjusted our commercialization efforts to incorporate virtual sales meetings and increased digital sales and marketing, those efforts may be less effective than in-person meetings to promote use of our products.

Although the spread of COVID-19 and actions taken to contain it lessened in the first quarter of 2021, if infection rates rise and/or if significant action is taken to contain the pandemic, we will likely experience test volume decreases and challenges for our sales force and efforts to recruit participants in studies, and our business, results of operations and financial condition are likely to be adversely affected. To the extent our testing volumes decrease and/or we are unable to collect from patient payers, our revenues, cash flows from operations and liquidity will be adversely impacted. There is no assurance that sales or collections will return to normal levels during 2021 or at any time thereafter.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

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 2021. 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 2019 and 2020 was 12,898 and 13,557, 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 for our products and services or changes in reimbursement rates could materially and adversely affect our business, financial condition and results of operations. In addition, changes in medical society guidelines can also adversely affect payers and result in a change in coverage.

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, Aspira GenetiX and Aspira Synergy 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, Aspira GenetiX and Aspira Synergy 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 our products or if third-party payers change their coverage or reimbursement policies with respect to our products, our business, financial condition and results of operations could be materially adversely affected.

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 within our laboratory, as well as products that are offered in a decentralized structure (Aspira Synergy), 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, as well as failure to complete analytical and clinical validation studies and failure to demonstrate sufficient clinical utility to continue to build positive medical policy among payers.

We are currently developing multiple tests as LDTs, and intend to develop and perform LDTs at ASPiRA LABS in the future. Should FDA disagree that our tests are LDTs or decide to regulate LDTs in the future, commercialization of our diagnostic tests may be adversely affected, which would negatively affect our results of operations and financial condition.

We also intend to develop and perform LDTs at ASPiRA LABS in the future. The FDA considers an LDT to be a test that is designed, developed, validated, and used within a single laboratory. The FDA has historically taken the position that it has the authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act ("FDC Act"), but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval or clearance of LDTs, it has generally chosen not to enforce those requirements to date. Separately, the Centers for Medicare and Medicaid Services oversees clinical laboratory operations through the 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, by either giving FDA explicit authority to do so or, alternatively, stating that FDA does not have authority to regulate LDTs, is difficult to predict. In March 2020, the Verified Innovative Testing in American Laboratories ("VITAL") Act of 2020 was introduced in the Senate, which would expressly shift the regulation of LDTs from FDA to CMS. If VITAL or a similar statute were to be enacted, it could mean that the FDA regulatory burden would decrease, but could also potentially result in new CMS

requirements for LDTs.

In August 2020, the United States Department of Health and Human Services ("HHS") announced that FDA will no longer require premarket review of LDTs absent notice-and-comment rulemaking. HHS rescinded all prior guidance documents and informal statements of policy concerning LDTs. FDA may, in the future, seek to regulate LDTs through notice-and-comment rulemaking, or Congress may act to provide further direction on the regulation of LDTs and substantially modify the regulation of IVDs. The recent change in presidential administration in January 2021 could result in a change in HHS policy with respect to LDTs which could lead to more active FDA regulation of our tests.

In the meantime, the regulation by the FDA of our tests that are positioned as LDTs remains uncertain. If FDA premarket review or approval is required for any of the tests we are developing or may develop in the future as LDTs, 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, approval or de novo classification. Our business, results of operations and financial condition would be negatively affected until such review were completed and clearance, approval or de novo classification to market were obtained.

If premarket clearance, approval or de novo classification is required by the FDA or if we decide to voluntarily pursue FDA premarket clearance, approval or de novo classification of our future LDTs, there can be no assurance that any tests we develop in the future will be cleared, approved or classified on a timely basis, if at all. Obtaining FDA clearance, approval or de

novo classification 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.

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 OVASight 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, Aspira GenetiX and Aspira Synergy 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, Aspira GenetiX and Aspira Synergy 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 these products 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, Becton Dickinson, Abbott Laboratories, Exact Sciences (Thrive), Grail, Anixa, Angle and InterVenn 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 any of these products in efficacy but is priced at a lower point, we and/or our strategic partners may have to lower the price of that product 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 authorize 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 authorized by FDA pursuant to either the premarket notification pathway, known as 510(k) clearance, the *de novo* classification pathway, or the PMA pathway. The FDA issued a de novo authorization for OVA1 in September 2009, and we commercially launched OVA1 in March 2010. In March 2016, we received FDA 510(k) clearance for a second-generation biomarker panel known as OVA1 Next Generation, which we call OVERA. OVA1 was the first FDA-cleared blood test for the pre-operative assessment of ovarian masses. With respect to devices reviewed through the 510(k) process, we may not market a device until it is determined that our product is 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 *de novo* classification, 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, 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 determines that a PMA is required for any of our potential future clinical products, the application will require extensive clinical studies, manufacturing information and could require review by an FDA advisory panel comprising 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 submission or denial of the application. We cannot assure that any necessary 510(k) clearance or PMA 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 granted the request for de novo classification for OVA1 in September 2009. Post-market surveillance studies were conducted to further analyze performance of OVA1 and OVERA. These studies have been completed and closed with the FDA.

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 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 2019 and 2020, 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.

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.

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 or the assessment of human health must be certified under CLIA and licensed or permitted 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. The principal sanction under CLIA is suspension, limitation, or revocation of a lab's CLIA certificate. CMS may also impose the following alternative sanctions: (a) directed plan of correction, (b) state onsight monitoring, and/or c) civil monetary penalty. In addition, CMS may bring suit to enjoin any activity of any laboratory that has been found with deficiencies during a survey if CMS has reason to believe that continuation of the activity would constitute a significant hazardd to the public health. Finally, criminal sanctions may be imposed on an individual who is convicted of

intentionally violating any CLIA requirement.

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.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have significant net operating loss ("NOL") carryforwards as of December 31, 2020 for which a full valuation allowance has been provided due to our history of operating losses. Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state provisions may restrict our ability to use our NOL carryforwards to offset taxable income due to ownership change limitations occurring in the past or that could occur in the future. These ownership changes may also limit the amount of tax credit carryforwards that can be utilized annually to offset future tax liabilities.

Legislation commonly referred to as the Tax Cuts and Jobs Act (H.R. 1) was enacted on December 22, 2017. As a result of the Tax Cuts and Jobs Act of 2017, federal NOLs arising before January 1, 2018, and federal NOLs arising after January 1, 2018, are subject to different rules. The Company's pre- 2018 federal NOLs will expire in varying amounts from 2021 through 2037, if not utilized and can offset 100% of future taxable income for regular tax purposes. Any federal NOLs arising after January 1, 2018, can generally be carried forward indefinitely and can offset up to 80% of future taxable income. State NOLs will expire in varying amounts from 2021 through 2037 if not utilized. The Company's ability to use its NOLs during this period will be dependent on the Company's ability to generate taxable income, and the NOLs could expire before the Company generates sufficient taxable income.

We believe we have experienced ownership changes in the past for purposes of these limitations, and we estimate that a substantial portion of our existing federal NOL and tax credit carryforwards are subject to annual limitation. Additional issuances or sales of our common stock, or certain other transactions involving our stock that are outside of our control, could cause additional ownership changes. Any current or future limitation on the use of our NOLs or tax credit carryforwards could, depending on the extent of such limitation, result in our retaining less cash during any year in which we have taxable income than we would be entitled to retain if such limitations did not apply, which could adversely impact our results of operations and financial condition.

RISKS RELATED TO INTELLECTUAL PROPERTY AND PRODUCT LIABILITY

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

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

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

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

If third parties engage in activities that infringe on our proprietary rights, we may incur significant costs in asserting our rights, and the attention of our management may be diverted from our business. We may not be successful in asserting our proprietary patient 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 may not be successful in asserting our proprietary trademark rights, which could result in significant rebranding costs, not being able to obtain a federal trademark registration, or a court holding that the competitor is not infringing, any of which may harm our competitive position. We cannot be sure that competitors will not use a similar mark.

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 a third party were to assert claims that we are violating its trademarks, we might incur substantial costs defending ourselves in lawsuits against charges of trademark infringement. 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 mark. We may also be required to rebrand or enter into a co-existence agreement with a third party, which may be commercially restrictive or unreasonable.

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.

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 common stock and our stockholders' ability to obtain liquidity in their shares of our common stock. 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 publicly available information, provided on Schedules 13D and 13G, as amended, filed on February 10, 2021 and February 11, 2021, we estimate that a total of six persons beneficially own approximately 58.35% of our outstanding common stock. Under the May 2013 stockholders agreement, two of these persons have the right to designate a director to be nominated by us to serve on our Board of Directors, and one of these persons has exercised this right. 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 involving us. In addition, 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. During the 12 months ended December 31, 2020, the trading price of our common stock ranged from a high of $6.75 per share to a low of $0.53 per share. The trading price of our common stock 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, Aspira GenetiX or Aspira Synergy;
- 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;
- failure to complete clinical studies that validate clinical utility sufficiently to increase positive medical policy among payers at large;
- publicity regarding actual or potential discoveries of biomarkers by others;
- comments or opinions by securities analysts or stockholders;
- the inclusion of our common stock in stock market indices such as the Russell 3000 Index;
- conditions or trends in the pharmaceutical, biotechnology or life science industries;
- announcements by us of significant acquisitions and divestitures, strategic partnerships, joint ventures or capital commitments;
- developments regarding our patents or other intellectual property or that of our competitors;
- litigation or threat of litigation;
- additions or departures of key personnel;
- limited daily trading volume;
- economic and other external factors, disasters or crises; and
- our announcement of future 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 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 March 19, 2021, we had 111,716,852 shares of our common stock outstanding and 4,485,776 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 9,975,168 shares of our common stock that were subject to outstanding options.

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

GENERAL RISKS

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.

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

We may seek to raise additional capital through the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. The availability of financing opportunities will depend, in part, on market conditions, and the outlook for our business. Any future issuance of equity securities or securities convertible into equity could result in substantial dilution to our stockholders, and the securities issued in such a financing may have rights, preferences or privileges senior to those of our common stock. If we are unable to obtain additional capital, we may not be able to continue our sales and marketing, research and development, distribution or other operations on the scope or scale of our current activity.

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, weather related supply chain delivery disruptions, 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.

The operation of ASPiRA LABS and our Aspira Synergy business 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.

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.

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.

	Approximate	**Lease Expiration**

Location	Square Feet	Primary Functions	Date
Austin, Texas	4,218 sq. ft.	ASPiRA LABS facility, research and development, clinical and regulatory and administrative offices	January 31, 2022
Trumbull, Connecticut	10,681 sq. ft.	Administrative offices	June 30, 2026

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 "AWH."

On March 29, 2021, there were 95 registered holders of record of our common stock. The closing price of our common stock on March 29, 2021was $6.58.

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 Aspira'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, 2020, options to purchase 4,776,503 shares of common stock remained outstanding under the 2010 Plan.

2019 Plan. The 2019 Plan is administered by the Compensation Committee of Aspira'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 Aspira's common stock under the 2019 Plan. At December 31, 2020, options to purchase 3,442,109 shares of common stock remained outstanding under the 2019 Plan.

The number of shares of Aspira'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, 2020, were as follows:

	Number of	Number of Securities Remaining Available for Future

Plan Category	Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Issuance Under Equity Compensation Plans (Excluding Shares Reflected in First Column)
Equity compensation plans approved by security holders	8,212,112	$ 1.49	6,504,934
Equity compensation plans not approved by security holders	-	-	-
Total	8,212,112		6,504,934

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-22 of this Annual Report on Form 10-K, and "Risk Factors", which are discussed in Item 1A. The statements below contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act. See "Forward-Looking Statements" on page 1 of this Annual Report on Form 10-K.

Overview

Our core mission is 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.

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 2021, in addition to our core physician-based sales team, we constructed and launched four net new verticals: Health Systems, Integration, Specialty and Customer Experience. The Health Systems team, accompanied by the Integration team, will pursue integration into the five segments of the healthcare system: Clinical, Operational, Financial, Informatics and Administrative; whereas the Specialty team will be driving large scale adoption of our decentralized technology transfer platform, Aspira Synergy. We expect Aspira Synergy will expand our breadth and reach of access for all Aspira products, as every commercialized product as well as pipeline innovations, will be blended into our Aspira Synergy platform.

We are focused on commercializing our products 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, which allows tests to be deployed internationally as well as run locally in the United States at major customer sites. In 2021, we plan to more fully commercialize OVA1plus by utilizing select partnerships for distribution, managed care coverage in select markets, plus our sales force (in our Core, Health Systems, and Specialty verticals) and increased adoption in our existing customer base. We also plan to develop an LDT product series of diagnostic algorithms that will include not only biomarkers, but also genetics, clinical risk factors, other diagnostics and patient history data in order to boost predictive value. The first diagnostic algorithm LDT, branded as OVASight, and formerly referred to as OVANex, focuses on monitoring women with pelvic masses. We expect OVASight to be available for commercial use in late 2021. The second diagnostic algorithm, EndoCheck, which will be an aid in the diagnosis of endometriosis. We also plan to expand our portfolio of products to include OVAInherit, which is the basis for those patients who are genetically predisposed to ovarian cancer. This algorithm will include genetics, proteins and other modalities to assess such 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, OVA1plus or Aspira GenetiX 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.

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 6, in March 2016, the Company entered into a loan agreement (as amended on March 7, 2018 and April 3, 2020, the "Loan Agreement") with the State of Connecticut Department of Economic and Community Development (the "DECD"), pursuant to which it may borrow up to $4,000,000 from the DECD.

The loan may be prepaid at any time without premium or penalty. An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. On December 3, 2020, the Company received a disbursement of the remaining $2,000,000 under the Loan Agreement, as the Company achieved the target employment milestone necessary to receive an additional $1,000,000 under the Loan Agreement and the DECD determined to fund the remaining $1,000,000 under the Loan Agreement after concluding that the required revenue target would likely have been achieved in the first quarter of 2020 in the absence of the impacts of COVID-19.

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

On April 10, 2020, the Company received a stimulus check of approximately $89,000 from the U.S. Department of Health and Human Services pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act").

As discussed in Note 6, on May 1, 2020, the Company obtained a loan (the "PPP Loan") from BBVA USA in the aggregate amount of $1,005,767, pursuant to the Paycheck Protection

Program (the "PPP"), which was established under the CARES Act, as administered by the U.S. Small Business Administration (the "SBA").

As discussed in Note 7, during June 2020, all of the warrants from the 2017 private placement were exercised. The Company received $5,058,608 in aggregate proceeds from the exercise of the warrants.

As discussed in Note 7, on July 20, 2020, the Company completed a private placement of Aspira common stock for net proceeds of $10.6 million, after deducting expenses related to the private placement.

As discussed in Note 12, on February 8, 2021, the Company completed a public offering (the "2021 Offering"), resulting in net proceeds of approximately $48.4 million, after giving effect to underwriting discounts but before expenses.

As discussed in Note 6, in March 2021, the Company applied for forgiveness of the PPP Loan, but there is no assurance that all or a portion of the PPP Loan will be forgiven.

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 $440,066,000. The Company also expects to incur a net loss and negative cash flows from operations for 2021.

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 Aspira's common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to Aspira'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 in 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 by reference.

Recent Developments

Leadership Updates

Effective November 9, 2020, the Company appointed Dr. Sandra Brooks to its board of directors, who was subsequently appointed to serve on its Compensation Committee of the board of directors.

On November 10, 2020, we announced the appointment of the following five new members to our executive leadership team: Dr. Elena Ratner, Global Chief Medical Advisor, Clinical and Translational Medicine; Kaile Zagger, Chief Operating Officer; Dr. Lesley Northrop, Chief Scientific Officer; Dr. Gary Altwerger, Global Deputy Chief Medical Advisor, Clinical and Translational Medicine; and Dr. Diane Powis, a Chief Spokeswoman.

On December 10, 2020, James S. Burns, a director of the Company's board of directors, retired from the Company's board of directors.

Effective February 17, 2021, the Company appointed Nicole Sandford to its board and its Audit Committee.

Effective March 19, 2021 the Company appointed Nicole Sandford to its Nominating and Governance Committee.

In the first quarter of 2021, we formed our own internal patient advisory board, led by our Chief Spokeswoman, Dr. Diane Powis. This board includes ovarian cancer patients and survivors whose mission is to lead how we serve and educate patients early in the process.

Business, Product and Coverage Updates

On March 11, 2020, we entered into an Amendment No. 4 to Testing and Services Agreement (the "Amendment") with Quest Diagnostics, Incorporated ("Quest Diagnostics"). The Amendment amends that certain Testing and Services Agreement, dated as of March 11, 2015 (as previously amended as of April 10, 2015, March 11, 2017 and March 1, 2018 (the "TSA"). The purpose of the Amendment was to extend the term of the TSA from March 11, 2019 to March 11, 2023 and for the Company to pay an annual fee of $75,000 for the services of a part-time Quest Diagnostics project manager.

On April 1, 2020, we commenced submission of claims under our preferred in-network contract with Cigna and are now receiving reimbursement of our OVA1, OVERA and Aspira GenetiX tests at the contracted rate.

On April 14, 2020, we announced that we are credentialed with Florida's State Medicaid program for an estimated additional 3.6 million credentialed Medicaid lives.

On September 18, 2020, AbbVie Inc. provided the Company with certain serum samples collected and tested as part of AbbVie Inc.'s clinical trials. The Company plans to use the samples in its upcoming EndoCheck product validation trial. EndoCheck will be designed as a simple blood test to aid in the detection of endometriosis and, as such, will be less invasive than current detection methods, which require a surgical biopsy. On September 18, 2020, AbbVie Inc. also provided the Company with additional data metrics, including patient demographics, endometriosis surgical pathology diagnoses, and other clinical metrics.

On October 14, 2020, we announced that we are a participating provider with Anthem BlueCross BlueShield of Georgia, which has an estimated additional 3.3 million members across the state. As of December 31, 2020, we have approximately 173 million covered lives in the U.S.

On November 19, 2020, we announced that we entered into a collaborative research agreement with Baylor Genetics to co-develop a novel ovarian cancer early detection test.

In the first quarter of 2021, we submitted an application to the FDA under its Breakthrough Devices Program for our diagnostic algorithm, EndoCheck, and expect to have a dialogue with the FDA in the second quarter of 2021.

In the first quarter of 2021, we announced that we entered into an agreement with Dana Farber Cancer Institute, Brigham and Women's Hospital and Medical University Lodz to evaluate their jointly-developed novel microRNA technology in combination with current Aspira technologies, for the development of a highly sensitive and specific early detection test for women with a high-risk of ovarian cancer.

In the first quarter of 2021, we are continuing to increase our investment in research and development, and one of our key investments is our efforts on closing the disparity gap in women's healthcare specific to the diagnostic accuracy of ovarian cancer detection. We have five active sites enrolled in our disparity clinical study; the most recent addition was Wayne State University in Detroit Michigan as our first National Cancer Institute site.

In the first quarter of 2021, we submitted an abstract to the American Society for Clinical Oncology for their early June 2021 conference, and will be publishing both the analytical and clinical validation findings in the third quarter of 2021.

In the first quarter of 2021, we announced coverage by New York State Medicaid – one of the larger Medicaid populations in the U.S., covering 33% of the population in the state. This will bring our total covered lives to approximately 179M or 54% of the U.S. population as of April 1, 2021.

In the first quarter of 2021, we presented at a Congressional Briefing "Advancing Health Outcomes for Women and Minorities." We delivered a call to action for OVA1 as the standard of care for ovarian cancer risk assessment for Caucasian and non-Caucasian women and the need for funding large race and ethnicity-based trials.

Branding and Listing Updates

On June 9, 2020, we announced that our common stock joined the broad-market Russell 3000® Index by FTSE Russell, effective after the U.S. stock market opening on

June 29, 2020.

On June 11, 2020, we announced that we changed our name from Vermillion, Inc. to Aspira Women's Health Inc., and our common stock would be listed on the Nasdaq Capital Market under the symbol "AWH."

In the fourth quarter of 2020, we launched a digital and media campaign to strengthen our brand identity, as well as increase awareness of the advantages of our OVA1 test, including early detection and racial disparities in detection when compared with CA125.

COVID-19 Pandemic

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. Patient enrollment for our planned research studies has been lower due to the impact of closures and restricted travel, which has led to delays in the completion of such studies. Our commercial efforts to enter into decentralized arrangements with large healthcare networks and supergroups have continued to move forward. However, finalization of such deals have been slowed by the pandemic. In addition, many conventions and industry conferences have been canceled.

As a result of the COVID-19 pandemic and actions taken to contain it, the majority of our non-laboratory employees have been working remotely since March 2020, and we expect that they will continue to do so until the number of daily COVID-19 cases in the areas surrounding our offices consistently level off or declines. In terms of business continuity, our lab operations require on site essential employees. As previously disclosed, we have put in place staffing and reagent contingency plans to ensure there is no down time at our lab. We believe the lab could continue to operate in the event any isolated infection were to impact a portion of the workforce. In addition, as of the date of the filing of this Form 10-K, we have approximately four months of reagents, one of our key testing supplies, in stock, depending on volume of tests performed, and we are working with the manufacturer to ensure a consistent supply over the next six months.

We are committed to following recommended physical and social distancing guidelines in order to reduce the risk of infection for our employees. We have also decreased our travel and convention-related expenses. We have taken several measures to reduce the impact of the COVID-19 related closures and quarantines. For example, because our salespeople have experienced limitations on their ability to physically visit physician offices, we have implemented other means of coverage such as virtual sales representative meetings and increased digital sales and marketing. In March 2020, our sales team began making in-person calls to customers as determined on a state-by-state basis, in accordance with local guidelines. We have developed protocols and training for our team where physical visits are allowed to help ensure employee, customer and patient safety.

In the fourth quarter 2020, we experienced a recovery in our test volume, such that when comparing the average number of tests per business ordering day in February 2020, the last full calendar month before COVID-19 significantly impacted the United States, to the average number of tests per business ordering day in December 2020, our test volume was back to approximately 93% of pre-COVID-19 levels. Given the potential for future resurgences of COVID-19 cases and the variety of federal and state actions taken to contain them, we are unable to estimate the potential future impact of the COVID-19 pandemic on our business, results of operations or cash flows as of the date of this filing.

On March 27, 2020, the U.S federal government enacted the CARES Act. The CARES Act is an emergency economic stimulus package in response to the coronavirus outbreak which, among other things, provided loans, guarantees and subsidies to qualifying businesses and contained numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. We do not expect these tax provisions to have a material impact on our financial statements.

On April 10, 2020, we received a stimulus check of approximately $89,000 from the U.S. Department of Health and Human Services pursuant to the CARES Act.

On May 1, 2020, we were granted the PPP Loan from BBVA USA in the aggregate amount of $1,005,767, pursuant to the PPP, which was established under the CARES Act as administered by the SBA. We believe we are using the proceeds of the PPP Loan in a manner that qualifies for complete forgiveness of the PPP Loan but caution that there can be no assurance that all or any portion of the PPP Loan will be forgiven. In March 2021, we applied for forgiveness of the PPP Loan. See “Liquidity and Capital Resources” for more information.

We had previously planned to offer COVID-19 antibody and antigen testing in connection with our pre-surgical test offering, as physicians had requested these tests to solve for shortages of testing on the local level. In the fourth quarter of 2020, we decided not to proceed with adding COVID-19 antibody and antigen testing given such tests are now readily available to our physician partners at their respective hospitals or otherwise.

Results of Operations – Year Ended December 31, 2020 as compared to Year Ended December 31, 2019

The Company's selected summary financial and operating data for the years ended December 31, 2020 and 2019 were as follows:

	Year Ended December 31,		Increase (Decrease)	
(dollars in thousands)	**2020**	**2019**	**Amount**	**%**
Revenue:				
Product	$ 4,530	$ 4,404	$ 126	3
Genetics	108	22	86	391
Service	13	112	(99)	(88)
Total revenue	4,651	4,538	113	2
Cost of revenue:				
Product	2,500	2,378	122	5
Genetics	898	295	603	204
Service	17	670	(653)	(97)
Total cost of revenue	3,415	3,343	72	2
Gross profit	1,236	1,195	41	3
Operating expenses:				
Research and development	2,104	1,018	1,086	107
Sales and marketing	8,843	9,645	(802)	(8)
General and administrative	8,270	5,810	2,460	42
Total operating expenses	19,217	16,473	2,744	17
Loss from operations	(17,981)	(15,278)	(2,703)	18
Interest income, net	10	59	(49)	(83)
Other income (expense), net	66	(18)	84	467
Net loss	$ (17,905)	$ (15,237)	$ (2,668)	18

Product Revenue. Product revenue was $4,530,000 for the year ended December 31, 2020, compared to $4,404,000 for the same period in 2019. Revenue for ASPiRA LABS is recognized when the OVA1, OVERA, or OVA1plus test is completed based on estimates of what we expect to ultimately realize. The 3% product revenue increase is primarily due to an increase in OVA1 test volume compared to the prior year, partially offset by a lower average revenue per test. We expect revenue to improve in 2021 due to test volumes returning to pre COVID-19 levels, provided that the COVID-19 pandemic does not further escalate and result in new quarantines and state closures. The duration of the pandemic and efforts to contain it remains uncertain.

The number of OVA1plus tests performed increased 5% to approximately 13,557 OVA1plus tests during the year ended December 31, 2020 compared to approximately 12,898 OVA1plus tests for the same period in 2019. The volume increase was primarily due to our commercialization investment, partially offset by decreases in test volume during certain periods of 2020 as a result of the COVID-19 pandemic and efforts to contain it.

The revenue per OVA1plus test performed decreased to approximately $334 compared to $341 for the same period in 2019. This decrease was primarily driven by a decrease in payments by patient payers. Through insourcing our billing function, which we completed in February 2020, we expect to increase the collections from patient payers. We expect that the broader economic impacts of the COVID-19 pandemic will continue to have an effect on our collections from patient payers.

Genetics Revenue. Genetics revenue was $108,000 for the year ended December 31, 2020, compared to $22,000 for the same period in 2019. We launched the Aspira GenetiX product in the fourth quarter of 2019. Revenue for Aspira GenetiX is recognized when the Aspira GenetiX test is completed based on estimates of what we expect to ultimately realize. The 391% genetics revenue increase is primarily due to an increase in Aspira GenetiX test volume as we launched this product in the fourth quarter of 2019, as well as a higher revenue per test. We expect revenue to improve in 2021 due to continued commercialization investment for the Aspira GenetiX product, provided that the COVID-19 pandemic does not further escalate and result in new quarantines and state closures. The duration of the pandemic and efforts to contain it remains uncertain.

The number of genetics tests performed increased 220% to approximately 307 Aspira GenetiX tests during the year ended December 31, 2020 compared to approximately 96 Aspira GenetiX tests for the same period in 2019. The volume increase was primarily due to our commercialization investment, partially offset by decreases in test volume during certain periods of 2020 as a result of the COVID-19 pandemic and efforts to contain it.

Service Revenue. Service revenue was $13,000 for the year ended December 31, 2020 compared to $112,000 for the same period in 2019. Revenue for ASPiRA IVD is recognized once certain revenue recognition criteria has been met. Substantially all projects with ASPiRA IVD were finalized during the fourth quarter of 2019 and the subsidiary's operations were largely completed. Some final project closure costs were recognized in 2020, as well as charges to customers for billable project closure support. In 2020, the Company had service revenue from the fulfillment of one legacy IVD contract. The Company expects to continue to have future revenue from the single legacy IVD contracts in 2021. However, we do not expect any to be significant (see Note 1 to the financial statements included in Part II, Item 8 of this Form 10-K).

Cost of Revenue - Product. Cost of product revenue was $2,500,000 for the year ended December 31, 2020 compared to $2,378,000 for the same period in 2019, representing an increase of $122,000, or 5%, 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 genetics revenue, which consisted primarily of personnel costs and consulting expense after the launch of Aspira GenetiX, was $898,000 for the year ended December 31, 2020 compared to $295,000 for the same period in 2019. Aspira GenetiX was launched in late 2019, with the majority of the $295,000 comprising 2019 costs related to personnel and consulting expense.

Cost of Revenue - Service. Cost of service revenue was $17,000 for the year ended December 31, 2020 compared to $670,000 for the same period in 2019. The 97% decrease was due to the substantial wind down of our ASPiRA IVD subsidiary in 2019, partially offset by costs related to project closure support and legacy IVD contracts.

Research and Development Expenses. Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses for the year ended December 31, 2020 increased by $1,086,000, or 107%, compared to the same period in 2019. This increase was primarily due to clinical utility and product development costs related to OVASight, our third-generation serial monitoring product, in 2020 as well as investments in bioinformatics and Aspira Synergy. We expect research and development expenses to increase in 2021, as a result of increased projects and clinical studies.

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 and other healthcare professionals regarding OVA1, OVERA, OVA1plus and Aspira GenetiX. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the year ended December 31, 2020 decreased by $802,000, or 8%, compared to the same period in 2019. This decrease was primarily due to lower commission payments and personnel related costs, as well as reductions in consulting and travel due to the COVID-19 pandemic. We expect sales and marketing expenses to increase in 2021, due to investing in key strategic hires and product portfolio expansion, as well as the continued re-openings relating to the COVID-19 pandemic, provided that the COVID-19 pandemic does not further escalate and result in new quarantines and state closures.

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 for the year ended December 31, 2020 increased by $2,460,000, or 42%,

compared to the same period in 2019. This increase was primarily due to an increase in legal expenses of $1,000,000, headcount and personnel expenses of $653,000, board of director fees of $359,000, consultant stock compensation of $244,000, and insurance costs of $118,000. We expect general and administrative expenses to increase slightly in 2021.

Other Income (Expense). Net other income (expense) for the year ended December 31, 2020 increased by $84,000, compared to the same period in 2019. Other income consists primarily of the stimulus check received from the U.S. Department of Health and Human Services of approximately $89,000.

Liquidity and Capital Resources

We plan to continue to expend resources selling and marketing OVA1, OVERA, OVA1plus and Aspira GenetiX and developing additional diagnostic tests and service capabilities.

On February 8, 2021, the Company completed the 2021 Offering resulting in net proceeds of approximately $48.4 million, after giving effect to underwriting discounts but before expenses.

On July 20, 2020, the Company completed a private placement pursuant to which certain investors purchased 3,150,000 shares of Aspira common stock at a per share price of $3.50. Net proceeds of the private placement were approximately $10.6 million, after deducting expenses related to the private placement.

In early June 2020, we issued 2,810,338 shares of our common stock upon the exercise of all of our outstanding warrants and received approximately $5.1 million in aggregate proceeds therefrom.

On May 1, 2020, the Company obtained the PPP Loan from BBVA USA in the aggregate amount of $1,005,767. The application for these funds required the Company to, in good faith, certify that the described economic uncertainty at the time made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to consider its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that was not significantly detrimental to the business. Under the terms of the CARES Act and the PPP, all or a portion of the principal amount of the PPP Loan is subject to forgiveness so long as, over the 24-week period following the Company's receipt of the proceeds of the PPP Loan, the Company uses those proceeds for payroll costs, rent, utility costs or the maintenance of employee and compensation levels. The PPP Loan, which was granted pursuant to a promissory note, matures on May 1, 2022. Any unforgiven portion of the PPP Loan bears interest at a rate of 1.000% per annum, payable monthly in equal installments commencing in May 2021. The Company applied for forgiveness of the PPP Loan in March 2021, but there is no assurance that all or a portion of the PPP Loan will be forgiven. The PPP Loan is subject to any new guidance and new requirements released by the Department of the Treasury.

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

On March 22, 2016, we entered the Loan Agreement with the DECD, pursuant to which we may borrow up to $4,000,000 from the DECD. 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.

The loan may be prepaid at any time without premium or penalty. An initial disbursement of $2,000,000 was made to us on April 15, 2016 under the Loan Agreement. On December 3, 2020, the Company received a disbursement of the remaining $2,000,000 under the Loan Agreement, as we achieved the target employment milestone necessary to receive an additional $1,000,000 under the Loan Agreement and the DECD determined to fund the remaining $1,000,000 under the Loan Agreement after concluding that the required revenue target would likely have been achieved in the first quarter of 2020 in the absence of the impacts of COVID-19.

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 by December 31, 2022. Conversely, if we are either unable to retain 25 full-time employees with a specified average annual salary for a consecutive two-year period or does not maintain our Connecticut operations through March 22, 2026, the DECD may require early

repayment of a portion or all of the loan plus a penalty of 5% of the total funded loan. For additional information, see Note 6 of our consolidated financial statements.

The Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2020 we had an accumulated deficit of $440,066,000 and stockholders' equity of $9,719,000. As of December 31, 2020, we had $16,631,000 of cash and cash equivalents and $6,400,000 of current liabilities. Working capital was $12,203,000 and $9,432,000 at December 31, 2020 and December 31, 2019, respectively. 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 through 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 2021.

We expect to incur a net loss and negative cash flows from operations in 2021. The impact of the COVID-19 pandemic and actions taken to contain it on our liquidity for 2021 cannot be estimated as of the date of this filing.

However, we believe that our cash and cash equivalents and our anticipated cash flows from operations will be sufficient to fund our operations for the next twelve months.

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

- resources devoted to sales, marketing and distribution capabilities;
- the rate of OVA1, OVERA, OVA1plus and Aspira GenetiX product 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 OVA1plus;
- the insurance payer community's acceptance of and reimbursement for our products;
- our plans to acquire or invest in other products, technologies and businesses;
- the market price of our common stock;
- the potential need to add study sites to access additional patients to maintain clinical timelines; and
- the impact of the COVID-19 pandemic and the actions taken to contain it, as discussed above.

Net cash used in operating activities was $14,734,000 for the year ended December 31, 2020, resulting primarily from the net loss reported of $17,905,000, which includes non-cash expenses in the amount of $1,548,000 related to stock compensation expense and $265,000 related to depreciation and amortization, offset by changes in accounts payable, accrued and other liabilities of $1,594,000.

Net cash used in operating activities was $12,965,000 for the year ended December 31, 2019, resulting primarily from the net loss reported of $15,237,000, which includes non-cash expenses in the amount of $1,193,000 related to stock compensation expense and $333,000 related to depreciation and amortization, offset by changes in accounts payable, accrued and other liabilities of $971,000, and changes in inventory expenses of $67,000.

Net cash used in investing activities was $490,000 and $133,000 for the year ended December 31, 2020 and 2019, respectively, which consisted primarily of property and equipment purchases.

Net cash provided by financing activities was $20.2 million for the year ended December 31, 2020, which resulted primarily from the proceeds from the PPP Loan of $1.0 million in May 2020, the proceeds from the exercise of the stock options of $1.6 million in June 2020, the proceeds from the exercise of warrants of approximately $5.1 million in June 2020, the proceeds from the private placement of approximately $10.6 million in July 2020, after deducting expenses related to the private placement, and the proceeds from the DECD loan of $2.0 million in December 2020. Net cash provided by financing activities was $15.4 million for the year ended December 31, 2019 which resulted primarily from the proceeds from the June 2019 public offering of $13.5 million after deducting underwriting discounts, commissions and other expenses. In July 2019, the underwriter exercised its option to purchase additional shares of Aspira common stock for net proceeds of $2.1 million, after deducting underwriting discounts, commissions and other expenses.

We have significant net operating loss ("NOL") carryforwards as of December 31, 2020 for which a full valuation allowance has been provided due to our history of operating losses. Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state provisions may restrict our ability to use our NOL credit carryforwards due to ownership change limitations occurring in the past or that could occur in the future. These ownership changes may also limit the amount of NOL credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

Legislation commonly referred to as the Tax Cuts and Jobs Act was enacted in December

2017. As a result of the Tax Cuts and Jobs Act of 2017, federal NOLs arising before January 1, 2018, and federal NOLs arising after January 1, 2018, are subject to different rules. The Company's pre-2018 federal NOLs will expire in varying amounts from 2021 through 2037, if not utilized and can offset 100% of future taxable income for regular tax purposes. Any federal NOLs arising after January 1, 2018, can generally be carried forward indefinitely and can offset up to 80% of future taxable income. State NOLs will expire in varying amounts from 2021 through 2037 if not utilized. The Company's ability to use its NOLs during this period will be dependent on the Company's ability to generate taxable income, and the NOLs could expire before the Company generates sufficient taxable income. The Company's ability to use NOL 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, as well as similar state specific provisions. These ownership changes may also limit the amount of NOL 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 NOL carryforwards before utilization and any NOL 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.

Off-Balance Sheet Arrangements

As of December 31, 2020, 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, 2020 and 2019, consolidated statements of operations for the years ended December 31, 2020 and 2019, consolidated statements of changes in stockholders' equity for the years ended December 31, 2020 and 2019, consolidated statements of cash flows for the years ended December 31, 2020 and 2019 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-21.

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, 2020.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2020, 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, 2020. 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, 2020 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, 2020, 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 March 25, 2021, Nancy Cocozza informed the Board that she would step down from the Board effective March 31, 2021. She did not advise the Company of any disagreement with the Company on any matters relating to its operations, policies or practices.

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", "Security Ownership of Certain Beneficial Ownership and Management" and "Delinquent Section 16(a) Reports" of our proxy statement relating to our annual meeting of stockholders to be held in 2021 (the "2021 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.aspirawh.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 2021 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 2021 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 2021 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 Aspira" of the 2021 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-22.

(b) EXHIBITS

Exhibit		Incorporated by Reference				Filed
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Herewith
3.1	Fourth Amended and Restated Certificate of Incorporation of Aspira Women's Health 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 Amendment to Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated June 11, 2020	8-K	001-34810	3.1	June 11, 2020	
3.4	Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock	8-K	001-34810	4.1	April 17, 2018	
3.5	Seventh Amended and Restated Bylaws of Aspira Women's Health Inc. effective February 26, 2021	8-K	001-34810	3.2	March 3, 2021	
4.1	Form of Aspira Women's Health 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 Aspira Women's Health Inc. (formerly 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	8-K	001-34810	10.2	May 14, 2013	

	Master, LP, Jack W. Schuler and other purchasers named therein					
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	10-K	001-34810	4.4	April 7, 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	10-K	001-34810	4.5	April 7, 2020	
4.6	Form of Indenture	S-3	333-252267	4.7	January 20, 2021	
4.7	Description of Aspira Women's Health 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. (formerly Ciphergen Biosystems, Inc.) and certain of its employees #	S-1/A	333-32812	10.9	August 24, 2000	
10.4	Vermillion, Inc. Amended and Restated 2010 Stock Incentive Plan #	8-K	001-34810	10.1	December 17, 2013	
10.5	Vermillion, Inc. Second Amended and Restated 2010 Stock Incentive Plan #	8-K	001-34810	10.1	June 22, 2015	
10.6	Vermillion, Inc. Second Amended and Restated	8-K	001-34810	10.1	June 27, 2018	

	2010 Stock Incentive Plan (as amended effective June 21, 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 Robert Beechey effective December 18, 2017 #	8-K	001-34810	10.1	December 14, 2017
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	10-K	001-34810	10.22	April 7, 2020	
10.23	Promissory Note, dated May 1, 2020, between Vermillion, Inc. and BBVA USA	8-K	001-34810	10.1	May 7, 2020	
10.24	Securities Purchase Agreement, dated July 1, 2020, by and between Aspira Women's Health Inc. and the investors listed on Schedule I thereto	8-K	001-34810	10.1	July 7, 2020	
14.1	Code of Business Conduct and 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.

ASPIRA WOMEN'S HEALTH INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Aspira Women's Health Inc.
Austin, Texas

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Aspira Women's Health Inc. (the "Company") as of December 31, 2020 and 2019, 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, 2020 and 2019, 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.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition – Determination of Transaction Price for Product Revenue

As described in Note 1 to the consolidated financial statements, the Company recognizes product

revenue upon completion of the test and delivery of results to the physician based on estimates of the amounts that will ultimately be realized. When determining the amount of revenue to be recognized, management applies judgment to determine the transaction price, which affects the amount of revenue recognized. The Company's product revenue for the year ended December 31, 2020 was $4.5 million.

We identified management's determination of the transaction price as a critical audit matter. Management's estimate considers various factors, including payment history, specifically amount and timing of payment, payer coverage, existence of reimbursement contracts, and current reimbursement rate information. Additionally, there is judgment in the distribution of patient accounts into portfolios with similar collection experience. Auditing these elements involved a high degree of auditor subjectivity and challenging auditor judgment.

The primary procedures we performed to address this critical audit matter included:

- Assessing the reasonableness of management's estimates, including the distribution of patient accounts into portfolios and the amounts collected by portfolio by (i) testing on a sample basis the underlying data by portfolio and ensuring that each item is grouped appropriately based on payer ID, (ii) reviewing pertinent supporting details including signed reimbursement contracts and publicly published pricing information, (iii) comparing historical estimated collection rates to actual amounts collected and (iv) recalculating the average collection period of each portfolio by testing on a sample basis the underlying historical collections data.
- Testing the completeness and accuracy of management's calculations by recalculating the estimated amount to be realized based on management's assumptions and reviewing source data on a sample basis for consistency with supporting documentation.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.
Austin, Texas
March 31, 2021

Aspira Women's Health Inc.
Consolidated Balance Sheets
(Amounts in Thousands, Except Share and Par Value Amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 16,631	$ 11,703
Accounts receivable	865	924
Prepaid expenses and other current assets	1,077	758
Inventories	30	25
Total current assets	18,603	13,410
Property and equipment, net	583	353
Right-of-use assets	406	52
Other assets	13	13
Total assets	$ 19,605	$ 13,828
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,149	$ 855
Accrued liabilities	3,618	2,588
Current portion long-term debt	999	193
Short-term debt	611	303
Lease liability	23	39
Total current liabilities	6,400	3,978
Non-current liabilities:		
Long-term debt	3,077	1,099
Lease liability	409	13
Total liabilities	9,886	5,090
Commitments and contingencies (Notes 3 and 6)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at December 31, 2020 and December 31, 2019; 104,619,876 and 97,286,157 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	105	97
Additional paid-in capital	449,680	430,802
Accumulated deficit	(440,066)	(422,161)
Total stockholders' equity	9,719	8,738
Total liabilities and stockholders' equity	$ 19,605	$ 13,828

See accompanying Notes to Consolidated Financial Statements

Aspira Women's Health Inc.
Consolidated Statements of Operations
(Amounts in Thousands, Except Share and Per Share Amounts)

	Year Ended December 31,	
	2020	**2019**
Revenue:		
Product	$ 4,530	$ 4,404
Genetics	108	22
Service	13	112
Total revenue	4,651	4,538
Cost of revenue[(1)]:		
Product	2,500	2,378
Genetics	898	295
Service	17	670
Total cost of revenue	3,415	3,343
Gross profit	1,236	1,195
Operating expenses:		
Research and development[(2)]	2,104	1,018
Sales and marketing[(3)]	8,843	9,645
General and administrative[(4)]	8,270	5,810
Total operating expenses	19,217	16,473
Loss from operations	(17,981)	(15,278)
Interest income, net	10	59
Other income (expense), net	66	(18)
Net loss	$ (17,905)	$ (15,237)
Net loss per share - basic and diluted	$ (0.18)	$ (0.18)
Weighted average common shares used to compute basic and diluted net loss per common share	100,723,303	86,595,581
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:		
(1) Cost of revenue	$ 106	$ 78
(2) Research and development	34	4
(3) Sales and marketing	228	125
(4) General and administrative	1,180	986

See accompanying Notes to Consolidated Financial Statements

Aspira Women's Health Inc.
Consolidated Statements of Changes in Stockholders' Equity
(Amounts in Thousands, Except Share Amounts)

See accompanying Notes to Consolidated Financial Statements

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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
Net loss				(17,905)	(17,905)
Common stock issued in conjunction with exercise of stock options	1,105,675	1	1,636	-	1,637
Common stock issued for restricted stock awards	267,706		182	-	182
Common stock issued in conjunction with warrant exercises	2,810,338	4	5,056	-	5,060
Common stock issued in conjunction with private placement, net of $384 in issuance costs	3,150,000	3	10,638	-	10,641
Stock compensation charge	-	-	1,366	-	1,366
Balance at December 31, 2020	104,619,876	$ 105	$ 449,680	$ (440,066)	$ 9,719

See accompanying Notes to Consolidated Financial Statements

Aspira Women's Health Inc.
Consolidated Statements of Cash Flows
(Amounts in Thousands)

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (17,905)	$ (15,237)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	26	-
Depreciation and amortization	265	333
Stock-based compensation expense	1,548	1,193
Loss on sale and disposal of property and equipment	3	55
Changes in operating assets and liabilities:		
Accounts receivable	59	(138)
Prepaid expenses and other assets	(319)	(209)
Inventories	(5)	67
Accounts payable, accrued liabilities and other liabilities	1,594	971
Net cash used in operating activities	(14,734)	(12,965)
Cash flows from investing activities:		
Purchase of property and equipment	(490)	(133)
Net cash used in investing activities	(490)	(133)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	-	13,521
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	(191)	(189)
Proceeds from issuance of common stock from exercise of stock options	1,637	17
Proceeds from DECD loan	2,000	-
Proceeds from PPP loan	1,005	-
Proceeds from exercise of warrants	5,060	-
Proceeds from private placement, net of issuance costs	10,641	-
Net cash provided by financing activities	20,152	15,441
Net increase in cash and cash equivalents	4,928	2,343
Cash and cash equivalents, beginning of period	11,703	9,360
Cash and cash equivalents, end of period	$ 16,631	$ 11,703
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	37	38
Supplemental disclosure of noncash investing and financing activities:		
Net increase in right-of-use assets	354	52
Net changes in accounts payable related to capital expenditures	8	-

See accompanying Notes to Consolidated Financial Statements

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

Organization and Basis of Presentation

Aspira Women's Health Inc., formerly known as Vermillion, Inc. ("Aspira" 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 currently markets and sells 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 leveraging the strengths of OVA1's (MIA) sensitivity and OVERA's (MIA2G) specificity; (4) Aspira GenetiX, a genetic test for gynecologic cancer risk, with a core focus on female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers; and (5) Aspira Synergy, the Company's new decentralized platform and cloud service technology. Through December 31, 2020, the Company's product and related services revenue was limited to revenue generated by sales of OVA1, OVA1plus and Aspira GenetiX. The Company sells OVA1 and OVA1plus through Aspira's wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, Aspira Labs, Inc. ("ASPiRA LABS").

The Company has historically 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 was a specialized, CLIA certified, laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. The Company has discontinued pursuing contracts for ASPiRA IVD and its contractual commitments were largely concluded in the fourth quarter of 2019.

Effective January 1, 2019, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2016-02, *Leases* ("ASU 2016-02"), and elected the package of practical expedients, including the hindsight practical expedient and the new transition approach permitted by ASU No. 2018-11, *Leases, Targeted Improvements* ("ASU 2018-11"). 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. ASU 2018-11 allows the Company not to reassess existing identification of leases, classification of leases or any initial direct costs. The Company has two office leases, one of which has as lease less than 12 months. 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.

Effective January 1, 2020, the Company adopted FASB ASU No. 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*, using the prospective transition approach, which allows the Company to change the accounting method without restating prior periods or booking cumulative adjustments. 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. The adoption of ASU 2018-15 did not have a material impact on the consolidated financial statements.

Liquidity

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 $440,066,000 and had limited liquidity at December 31, 2020. The Company also expects to incur a net loss and negative cash flows from operations for 2021.

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. In March 2020, the World Health Organization declared COVID-19, the disease caused by the novel coronavirus, a pandemic, and 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 a result of the COVID-19 pandemic and actions taken to contain it, the Company's test volume, and resulting revenue, decreased significantly in late March and the full month of April 2020 as fewer patients visited their physicians and elective surgeries were postponed as a result of closures. The Company saw some increases in its test volume towards the latter half of the second quarter and in the third quarter of 2020, and test volume trended back to pre-COVID-19 levels during the late third quarter 2020. In order to reduce the impact of limitations on visiting physician offices due to closures and quarantines, the Company implemented other mechanisms for reaching physicians such as virtual sales representative meetings and increased digital sales and marketing. Enrollment for future studies has been slower than originally planned due to the impact of current closures for some states. The full impact of the COVID-19 pandemic continues to evolve as of the date of this filing. As a result, the Company is unable to estimate the extent of the impact of the COVID-19 pandemic on its liquidity.

As discussed in Note 6, in March 2016, the Company entered into a loan agreement (as amended on March 7, 2018 and April 3, 2020, the "Loan Agreement") with the State of Connecticut Department of Economic and Community Development (the "DECD"), pursuant to which it may borrow up to $4,000,000 from the DECD.

The loan may be prepaid at any time without premium or penalty. An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. On December 3, 2020, the Company received a disbursement of the remaining $2,000,000 under the Loan Agreement, as the Company had we achieved the target employment milestone necessary to receive an additional $1,000,000 under the Loan Agreement and the DECD determined to fund the remaining $1,000,000 under the Loan Agreement after concluding that the required revenue target would likely have been achieved in the first quarter of 2020 in the absence of the impacts of COVID-19.

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

On April 10, 2020, the Company received a stimulus check of approximately $89,000 from the U.S. Department of Health and Human Services pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act").

As discussed in Note 6, on May 1, 2020, the Company obtained a loan (the "PPP Loan") from BBVA USA in the aggregate amount of $1,005,767, pursuant to the Paycheck Protection Program (the "PPP"), which was established under the CARES Act, as administered by the U.S. Small Business Administration (the "SBA").

As discussed in Note 7, during June 2020, all of the warrants from the 2017 private placement were exercised. The Company received $5,058,608 in aggregate proceeds from the exercise of the warrants.

As discussed in Note 7, on July 20, 2020, the Company completed a private placement of Aspira common stock for net proceeds of $10.6 million, after deducting expenses related to the private placement.

As discussed in Note 12, on February 8, 2021, the Company completed a public offering (the "2021 Offering"), resulting in net proceeds of approximately $48.4 million, after giving effect to the underwriting discounts but before expenses.

As discussed in Note 6, in March 2021, the Company applied for forgiveness of the PPP Loan, but there is no assurance that all or a portion of the PPP Loan will be forgiven.

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.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation with no material effect on the consolidated financial statements.

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 customers' 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 – OVA1, OVERA and OVA1plus: 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 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, 2020, there were no adjustments to estimates of variable consideration to derecognize revenue for services provided in a prior period. There were no impairment losses on accounts receivable recorded during the years ended December 31, 2020 and 2019.

Genetics Revenue – Aspira GenetiX: Under ASC 606, the Company's genetics revenue is recognized upon completion of the Aspira GenetiX 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 developments or changes that could impact reimbursement. These estimates require significant judgment by management as the Company has limited experience with such factors relating to Aspira GenetiX.

Service Revenue: The Company's service revenue was generated by performing IVD trial services for third-party customers. 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 does not expect to have any significant service

revenue going forward, as it largely wound down performing the ASPiRA IVD trial services in the fourth quarter of 2019. During 2020, the Company's service revenue was limited to the fulfillment of one legacy IVD contract. 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 $322,000 and $203,000 for the years ended December 31, 2020 and 2019, respectively.

Stock-Based Compensation

The Company records the fair value of non-cash stock-based compensation costs for stock options related to the 2019 Stock Incentive Plan ("2019 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 and accrued liabilities 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 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.

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 Aspira'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. The purpose of the 2020 amendment was to extend the term of the Testing and Services Agreement from March 11, 2019 to March 11, 2023 and for the Company to pay an annual fee of $75,000 for the services of a part-time Quest Diagnostics project manager.

NOTE 4: PROPERTY AND EQUIPMENT

The components of property and equipment as of December 31, 2020 and 2019 were as follows**:**

	December 31,	
(in thousands)	**2020**	**2019**
Machinery and equipment	$ 1,094	$ 841
Demonstration equipment	17	16

Computer equipment and software	1,194	1,094
Furniture and fixtures	154	144
Leasehold improvements	701	639
Gross property and equipment	3,160	2,734
Accumulated depreciation and amortization	(2,577)	(2,381)
Property and equipment, net	$ 583	$ 353

Depreciation expense for property and equipment was $265,000 and $333,000 for the years ended December 31, 2020 and 2019, respectively.

NOTE 5: ACCRUED LIABILITIES

The components of accrued liabilities as of December 31, 2020 and 2019 were as follows:

(in thousands)	December 31, 2020	2019
Payroll and benefits related expenses	$ 1,874	$ 1,229
Collaboration and research agreements expenses	616	350
Professional services	803	679
Other accrued liabilities	325	330
Total accrued liabilities	$ 3,618	$ 2,588

NOTE 6: COMMITMENTS, CONTINGENCIES AND DEBT

Long-term debt consisted of the following:

(in thousands)	Year Ended December 31, 2020	2019
DECD loan	$ 3,070	$ 1,292
PPP loan	1,006	-
Total debt	4,076	1,292
Less: Current portion	(999)	(193)
Total long-term debt	3,077	1,099

Coronavirus Aid, Relief, and Economic Security (CARES) Act and Paycheck Protection Program Loan

On May 1, 2020, the Company obtained the PPP Loan from BBVA USA in the aggregate amount of $1,005,767. The application for these funds required the Company to, in good faith, certify that the described economic uncertainty at the time made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to consider its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that was not significantly detrimental to the business. Under the terms of the CARES Act and the PPP, all or a portion of the principal amount of the PPP Loan is subject to forgiveness so long as, over the 24-week period following the Company's receipt of the proceeds of the PPP Loan, the Company uses those proceeds for payroll costs, rent, utility costs or the maintenance of employee and compensation levels. The PPP Loan, which was granted pursuant to a promissory note, matures on May 1, 2022. Any unforgiven portion of the PPP Loan bears interest at a rate of 1.000% per annum, payable monthly in equal installments commencing in May 2021. The Company applied for forgiveness of the PPP Loan in March 2021, but there is no assurance that all or a portion of the PPP Loan will be forgiven. The PPP Loan is subject to any new guidance and new requirements released by the Department of the Treasury.

Loan Agreement

On March 22, 2016, the Company entered into a loan agreement (as amended, the "Loan Agreement") with the DECD, pursuant to which the Company may borrow up to $4,000,000 from the DECD. 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.

The loan may be prepaid at any time without premium or penalty. An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. On December 3, 2020, the Company received a disbursement of the remaining $2,000,000 under the Loan Agreement, as the Company had achieved the target employment milestone necessary to receive an additional $1,000,000 under the Loan Agreement and the DECD determined to fund the remaining $1,000,000 under the Loan Agreement after concluding that the required revenue target would likely have been achieved in the first quarter of 2020 in the absence of the impacts of COVID-19.

Under the terms of the Loan Agreement, 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. Conversely, if the Company is either unable to retain 25 full-time employees with a specified average annual salary for a consecutive two-year period or does not maintain the Company's Connecticut operations through March 22, 2026, the DECD may require early repayment of a portion or all of the loan plus a penalty of 5% of the total funded loan.

As of December 31, 2020, the annual amounts of future minimum principal payments due under certain of the Company's contractual obligations are shown in the table below. Debt issuance costs for the DECD loan were $18,000. Debt related to the PPP Loan of $1,000,000 and that certain insurance promissory note of $611,000, as described below, are not included in the table below, as the PPP Loan is expected to be forgiven and the $611,000 insurance promissory note is cancelable.

	Payments Due by Period						
(in thousands)	**Total**	**2021**	**2022**	**2023**	**2024**	**2025**	**Thereafter**
DECD Loan	3,088	508	564	576	588	599	253
Total	$ 3,088	$ 508	$ 564	$ 576	$ 588	$ 599	$ 253

Insurance Notes

During 2020 and 2019, the Company entered into insurance promissory notes for the payment of insurance premiums at an interest rate of 3.88% and 4.49% respectively, with an aggregate principal amount outstanding of approximately $611,000 and $303,000 as of December 31, 2020 and 2019, respectively. The amount outstanding could be substantially offset by the cancellation of the related insurance coverage which is classified in prepaid insurance. These notes are payable in ten monthly installments with maturity dates of October 1, 2021 and October 1, 2020, respectively.

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, and the CLIA laboratory used for ASPiRA IVD services is located in Trumbull, Connecticut. In October 2020, the Company renewed the Austin, Texas lease for one additional year. The Company's renewed lease expires on January 31, 2022, with no automatic renewal or renewal option.

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. In September 2020, the Company exercised the renewal option for its Trumbull, Connecticut lease. The Company's renewed lease expires on June 30, 2026, with a five year renewal option. The Company is not reasonably certain that it will exercise the five year renewal option beginning on July 1, 2026.

The expense associated with these operating leases for the years ended December 31, 2020 and 2019 is shown in the table below (in thousands).

		Year Ended December 31	
Lease Cost	**Classification**	**2020**	**2019**
Operating rent expense			

	Cost of revenue	$	71	$	38
	Research and development		50		11
	Sales and marketing		29		35
	General and administrative		66		46
Variable rent expense					
	Cost of revenue	$	7	$	49
	Research and development		1		14
	Sales and marketing		45		41
	General and administrative		54		57

Based on our leases as of December 31, 2020, the table below sets forth the approximate future lease payments related to operating leases with initial terms of one year or more (in thousands).

2021	$ 63
2022	95
2023	106
2024	116
2025	123
2026	64
Total Operating Lease Payments	567
Less: Interest	(135)
Present Value of Lease Liabilities	$ 432

Weighted-average lease term and discount rate were as follows:

Weighted-average remaining lease term (in years)	5.5
Weighted-average discount rate	9.38%

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, Aspira 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, 2020 and 2019 totaled $181,000 and $176,000, 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 "2019 Underwriting Agreement") with William Blair & Company, L.L.C., as the sole underwriter (the "2019 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 2019 Underwriting Agreement, the Company agreed to issue and sell an aggregate of 18,750,000 shares of Aspira common stock offered by the 2019 Underwriter in a public offering at a price of $0.80 per share (the "2019 Offering"). The 2019 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 2019 Underwriting Agreement, the Company granted the 2019 Underwriter an option to purchase up to an additional 2,812,500 shares of Aspira common stock at the public offering price, less underwriting discounts and commissions. On July 2, 2019, the 2019 Underwriter exercised its option to purchase 2,812,500 shares of Aspira 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.

2020 Exercise of Warrants

On February 17, 2017, the Company issued certain warrants to purchase up to an aggregate of 2,810,338 shares of Aspira common stock at an exercise price of $1.80 per share in connection with a February 2017 private placement of Aspira common stock. The warrants were initially sold at a price of $0.125 per share of common stock underlying the warrants.

On June 1, 2020, following the 20th consecutive trading day for which the closing price per share of Aspira common stock, as reported on the Nasdaq stock market, exceeded the exercise price, the Company sent notice to the investors holding such warrants accelerating the expiration date of the warrants, in accordance with the terms thereof. Pursuant to the terms of the warrants, any portion of the warrants not exercised prior to such accelerated expiration date would become void and of no value.

As of June 9, 2020, all of the warrants were exercised. The Company issued 2,810,338 shares of Aspira common stock and received $5,060,000 in aggregate proceeds from the exercise of the warrants. As of the date of the issuance of these financial statements, there are no outstanding warrants for the purchase of Aspira common stock.

2020 Private Placement

On July 20, 2020, the Company completed a private placement pursuant to which certain investors purchased 3,150,000 shares of Aspira common stock at a price of $3.50 per share. Net proceeds of the private placement were $10.6 million, after deducting expenses related to the private placement of $384,000. The sale of common stock qualified for equity treatment under GAAP.

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, 2020 and 2019 was as follows:

(In thousands, except shares and per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
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)
Year ended December 31, 2020:			
Net loss available to common shareholders - basic	$ (17,905)	100,723,303	$ (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	$ (17,905)	100,723,303	$ (0.18)

Due to net losses for the years ended December 31, 2020 and 2019, 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, 2020 and 2019 were as follows:

	Year Ended December 31,	
	2020	**2019**
Stock options	8,212,112	6,612,878
Stock warrants	-	2,810,338
Unvested restricted stock awards	-	-
Potential common shares	8,212,112	9,423,216

NOTE 9: EMPLOYEE BENEFIT PLANS

2010 Stock Incentive Plan

The Company's employees, directors, and consultants were eligible to receive awards under the Vermillion, Inc. Second Amended and Restated 2010 Stock Incentive Plan, which was replaced by the 2019 Plan (as defined below) with respect to future equity grants. As of December 31, 2020, a total of 4,776,503 shares of Aspira common stock were reserved for issuance with respect to outstanding stock options.

2019 Stock Incentive Plan

At the Company'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 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, 2020, there were 10,492,283 shares of Aspira common stock available for future grants under the 2019 Plan. As of December 31, 2020, there were 3,442,109 shares of Aspira common stock subject to outstanding stock options and there were no outstanding restricted stock units.

The activity related to shares available for grant under the 2010 Plan and the 2019 Plan for the years ended December 31, 2020 and 2019 was as follows:

	2010 Stock Option Plan	2019 Stock Option Plan	Total
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
Options canceled	718,500	502,000	1,220,500
Options granted	-	(3,925,409)	(3,925,409)
Restricted stock units granted	-	(356,940)	(356,940)
Shares forfeited	(1,388,900)	-	(1,388,900)
Shares available at December 31, 2020	-	6,504,934	6,504,934

The stock option activity under the 2010 Plan and the 2019 Plan for the years ended December 31, 2020 and 2019 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
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
Granted	3,925,409	1.46		
Exercised	(1,105,675)	1.48		
Canceled	(1,220,500)	0.75		
Options outstanding at December 31, 2020	8,212,112	$ 1.49	$42,833,712	7.51
Shares exercisable:				
December 31, 2020	3,743,698	$ 1.56	$19,272,201	6.41
Shares expected to vest:				
December 31, 2020	4,468,414	$ 1.44	$23,561,533	8.91

The range of exercise prices for options outstanding and exercisable at December 31, 2020 is as follows:

Exercise Price	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Options Exercisable	Weighted Average Exercise Price
$ 0.47 - $ 0.68	2,157,468	$ 0.64	8.59	613,968	$ 0.61
0.71 - 1.29	3,012,383	1.11	7.93	1,039,133	1.18
1.31 - 2.83	2,102,197	1.87	5.64	1,750,572	1.80
2.87 - 4.80	940,064	3.88	7.84	340,025	3.23
$ 0.47 - $ 4.80	8,212,112	$ 1.49	7.51	3,743,698	$ 1.56

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2020	$ 3,439	$ 3,254
Year ended December 31, 2019	$ 8	$ 2,869

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, 2020 and 2019 were as follows:

	Year Ended December 31,	
	2020	**2019**
Dividend yield	- %	- %
Volatility	84 %	79 %
Risk-free interest rate	0.71 %	2.30 %
Expected lives (years)	2.9	4.0
Weighted average grant date fair value	$ 0.87	$ 0.55

The allocation of employee and director stock-based compensation expense by functional area for the years ended December 31, 2020 and 2019 was as follows:

	Year Ended December 31,	
(in thousands)	**2020**	**2019**
Cost of sales	$ 96	$ 67
Research and development	33	4
Sales and marketing	162	122
General and administrative	924	942
Total	$ 1,215	$ 1,135

As of December 31, 2020, total unrecognized compensation cost related to unvested stock option awards was approximately $2,970,000 and the related weighted average period over which it is expected to be recognized was 2.72 years. As of December 31, 2020, there was no unrecognized compensation costs related to restricted stock units.

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 Company contributions under the 401(k) Plan. During the years ended December 31, 2020 and 2019, the Company did not make Company contributions to the 401(k) Plan.

NOTE 10: INCOME TAXES

During the preparation of the 2020 financial statements, immaterial errors were identified in the Company's previous deferred tax disclosures. The Company has determined that a revision was required to correct certain gross deferred tax assets to reflect the proper amount of federal net operating loss carryforwards, to properly include state income taxes, and to properly exclude uncertain tax credit carryforwards. Specifically, portions of the net operating losses ("NOLs") that are subject to Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382") limitations, but were not limited, were excluded from deferred tax assets which led to an

understatement of the deferred tax asset by $5,535,246 (tax effected); deferred state income taxes were not recorded, which led to an understatement of deferred tax assets of $2,466,759 (tax effected); and tax credit carryovers were incorrectly reflected, which led to an overstatement of deferred tax assets of $10,643,355 (tax effected). The net impact was an overstatement of deferred tax assets of $2,641,350. However, there was no net impact to the net deferred tax asset and tax expense as the change in deferred tax assets was offset completely by a corresponding adjustment to the Company's valuation allowance. For comparative purposes, the Company's 2019 tax disclosure has been revised to reflect the adjustment to the deferred tax assets and valuation allowance. The Company evaluated the errors and concluded the impact was not material. The effect of these revisions to the net deferred tax asset balance was zero, and the revision had no impact on the Company's consolidated balance sheet, statement of operations or statement of cash flows.

There was no income tax expense or benefit for the years ended December 31, 2020 or 2019 because of net losses during those years. These net losses were generated from domestic operations.

Domestic and foreign components of loss from continuing operations before income taxes for the years ended December 31, 2020 and 2019 were $17,905,000 and $15,236,000, respectively.

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2020 and 2019. There was no income tax expense or benefit for the years ended December 31, 2020 or 2019.

The components of net deferred tax assets (liabilities) at December 31, 2020 and 2019 were as follows:

	Year Ended December 31,	
(in thousands)	2020	2019
Deferred tax assets:		
Net operating losses	$ 32,740	$ 28,939
Amortization - R&D intangibles	2,495	2,810
Other	-	124
Total deferred tax assets	35,235	31,873
Valuation allowance	(35,195)	(31,873)
Deferred tax assets	$ 40	$ -
Deferred tax liabilities:		
Other	$ 40	$ -
Deferred tax liabilities	$ 40	$ -
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, 2020 and 2019 was as follows:

	Year Ended December 31,	
	2020	2019
Tax at federal statutory rate	21 %	21 %
State tax, net of federal benefit	1	1
Valuation allowance	(19)	(42)
Net operating loss and tax credit carryforwards	(2)	23
Permanent items	(1)	(1)
Other	-	(2)
Effective income tax rate	- %	- %

As a result of the Tax Cuts and Jobs Act of 2017, federal NOLs arising before January 1, 2018, and federal NOLs arising after January 1, 2018, are subject to different rules. The Company's pre-2018 federal NOLs will expire in varying amounts from 2021 through 2037, if not utilized and can offset 100% of future taxable income for regular tax purposes. Any federal NOLs arising after January 1, 2018, can generally be carried forward indefinitely and can offset up to 80% of future taxable income. State NOLs will expire in varying amounts from 2021 through 2037 if not utilized.

The Company's ability to use its NOLs during this period will be dependent on the Company's ability to generate taxable income, and the NOLs could expire before the Company generates sufficient taxable income.

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

The Company 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 and tax credit carryforwards before utilization and any net operating loss and tax credit carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the 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.

Provisional amounts

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 our 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 $35,200,000 and $31,900,000 at December 31, 2020 and 2019, respectively. The increase of approximately $3,300,000 between 2019 and 2020 is primarily due to adjustments to the domestic deferred tax assets related to net operating losses.

The Company files income tax returns in the U.S. and in various state jurisdictions with varying statutes of limitations. The Company has not been audited by the Internal Revenue Service or any state income or franchise tax agency. As of December 31, 2020, the Company's federal returns for the years ended 2017 through the current period and most state returns for the years ended 2016 through the current period are still open to examination. In addition, all of the net operating losses and research and development credits generated in years earlier than 2017 and 2016, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2019 reflect research and development carryforwards of $5,292,000 and $5,351,000, respectively. For the year ended December 31, 2020, the Company anticipates claiming additional research and development credits of $20,000 on its federal tax return and $45,000 on its California tax return.

As of December 31, 2020, the Company's gross unrecognized tax benefits are approximately $10,517,000 which are attributable to research and development credits. A reconciliation of the change in the Company's unrecognized tax benefits is as follows:

(in thousands)	Federal Tax	State Tax	Total
Balance at December 31, 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
Return to provision true up	-	-	-
Increase in tax position during 2020	20	45	65
Decrease due to expirations during 2020	(192)	-	(192)
Balance at December 31, 2020	$ 5,121	$ 5,396	$ 10,517

The increase for the year ended December 31, 2020 relates to a position taken in the current year. The increase for the year ended December 31, 2019 is related to tax positions taken during 2019 and prior years. If the $10.5 million of unrecognized income tax benefit is recognized, approximately $10.5 million would impact the effective tax rate in the period in which each of the benefits is recognized.

The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. The Company recognizes interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations and comprehensive loss. The Company has not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2020 and 2019. Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

NOTE 11: RELATED PARTY TRANSACTIONS

None.

NOTE 12: SUBSEQUENT EVENTS

On February 4, 2021, the Company entered into an underwriting agreement (the "2021 Underwriting Agreement") with William Blair & Company, L.L.C. and Truist Securities, Inc., as representatives of several underwriters (the "2021 Underwriters"), in connection with the underwritten public offering of 6,000,000 shares of the Company's common stock, par value $0.001 per share (the "2021 Firm Shares"), at a price to the public of $7.50 per share. The 2021 Underwriters purchased the 2021 Firm Shares at the public offering price per share, less the underwriting discount of $0.4875 per share.

Under the 2021 Underwriting Agreement, the Company granted the 2021 Underwriters an option to purchase up to an additional 900,000 shares of Aspira common stock, par value $0.001 per share (the "2021 Option Shares"), at the public offering price, less the underwriting discount of $0.4875 per share. On February 5, 2021, the 2021 Underwriters notified the Company that they were exercising this option in connection with the closing of the 2021 Offering. The 2021 Offering, including the 2021 Option Shares, closed on February 8, 2021 and resulted in net proceeds to the Company of approximately $48.4 million, after giving effect to underwriting discounts but before expenses.

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.

Aspira Women's Health Inc.

Date: March 31, 2021

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

Date: March 31, 2021

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

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

Name	Title	Date
/s/ Valerie B. Palmieri Valerie B. Palmieri	President and Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2021
/s/ Robert Beechey Robert Beechey	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2021
/s/ James T. LaFrance James T. LaFrance	Chairman of the Board of Directors	March 31, 2021
/s/ Sandra Brooks Sandra Brooks	Director	March 31, 2021
/s/ Nancy Cocozza Nancy Cocozza	Director	March 31, 2021
/s/ Veronica G. H. Jordan Veronica G. H. Jordan	Director	March 31, 2021
/s/ Nicole Sandford Nicole Sandford	Director	March 31, 2021
/s/ David Schreiber David Schreiber	Director	March 31, 2021