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

FORM 10-K

T ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2021 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 T

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 T

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 T 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 T 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 T	Smaller reporting company T
	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 T

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

The aggregate market value of voting common stock held by non-affiliates of the registrant is $477,546,462 and is based upon the last sales price as quoted on The NASDAQ Capital Market as of June 30, 2021.

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 T No ¨

As of March 18, 2022, the registrant had 112,138,741 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, 2021.

ASPIRA WOMEN'S HEALTH INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2021

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PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995.

These statements involve a number of risks and uncertainties. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements speak only as of the date on which this 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:

- 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 diseases, including additional pelvic disease conditions such as endometriosis and, benign pelvic mass monitoring in addition to genetics risk assessment, including breast and ovarian cancer hereditary risk assessment and carrier screening;
- our planned business strategy and strategic business drivers and the anticipated effects thereof, including partnerships such as those based on our Aspira Synergy product, as well as other strategies, specimen collaboration and licensing;
- plans to expand our existing products OVA1, OVERA, OVA1plus, Aspira GenetiX and Aspira Synergy on a global level, and to launch and commercialize our new products, OVAWatch (previously OVASight), EndoCheck and OVAInherit;
- 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 and secure contracts for Aspira GenetiX, OVAWatch, EndoCheck and OVAInherit separately and expand current coverage and secure contracts for OVA1;
- plans that would 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 or consolidate ASPiRA LABS' testing capabilities;
- expectations regarding continuing future services provided by Quest Diagnostics Incorporated ("Quest");
- plans to develop informatics products and develop and perform laboratory developed tests ("LDTs");
- FDA oversight changes of LDTs;
- plans to develop a race or 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;
- expectations regarding potential collaborations with governments, legislative bodies and advocacy groups to enhance awareness and drive policies to provide broader access to our tests;
- 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 research 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, as well as our offerings of Aspira GenetiX and Aspira Synergy platform;
expectations regarding our ability to launch new products we develop or license, co-market or acquire new products;
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 each of AbbVie Inc. serum samples and ObsEva S.A. plasma samples in EndoCheck product validation studies;
plans with respect to EndoCheck whether or not the FDA designates it a Breakthrough Device;
expected target launch timing for OVAWatch and Endocheck;
expectations regarding compliance with federal and state laws and regulations relating to billing arrangements conducted in coordination with laboratories;
plans to advocate for legislation and professional society guidelines to broaden access to our products and services; 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; 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; 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 laboratory 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 eradicate late-stage detection of ovarian cancer and to ensure that our solutions will meet the needs of women of all ages, races, ethnicities and stages of the disease. Our core patient goal is to develop a lifelong relationship with each patient, ensuring each woman has access to best-in-class diagnostics.

Our plan is to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological diseases. We plan to continue commercializing our new generation of technology as well as distribute our technology through our decentralized technology transfer service platform, known as "Aspira Synergy." We also intend to raise public awareness regarding the diagnostic superiority of OVA1 as compared to cancer antigen 125 ("CA125") for all women, but especially for Black women with adnexal masses, as well as the importance of machine learning algorithm development in ethnic populations. We also plan to advocate for legislation and professional society guidelines to provide broad access to our products and services.

Mission Statement: Aspira is transforming women's health with the discovery, development, and utilization of innovative testing options and bio-analytical solutions that help physicians assess risk, optimize patient management and improve gynecologic health outcomes for women. OVA1, which received *de novo* classification from the FDA, and OVERA, which is FDA-cleared, detect the risk of ovarian malignancy in women with adnexal masses via a non-invasive venipuncture. Our recently launched Aspira GenetiX^{SM} testing offers both targeted and comprehensive genetic testing options with a gynecologic focus. With over 10 years of experience in ovarian cancer risk assessment, Aspira has expertise in cutting-edge research to inform our next generation of products. Our focus is on delivering products that allow healthcare providers to stratify risk, facilitate early detection and optimize treatment plans.

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 (e.g., DNA, RNA or protein) 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 that provide information about the disease state with sufficient sensitivity and specificity to aid the physician considering treatment options for patients with complex diseases. Such assays are sometimes referred to as Multivariate Index Assays ("MIAs") and often utilize advanced algorithms based on logistic regression, pattern recognition and the like. Often, MIA 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 FDA. In the case of OVA1, the 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 develop diagnostic tests that detect genetic drivers at early stages, with the goal of improving survival rates. In clinical genetic testing, our approach is to target specific genomic indicators of disease that are well-established in scientific journals and publications. In this approach, offered by our Aspira GenetiX testing platform, we 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.

Science of Proteo "omics": 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. Proteo "omics" integrates protegenomic data from blood measurements of proteins with genomic and transcriptomic data, to understand the molecular drivers of the cancer, as measuring the three in combination strengthens the ability to diagnose cancer early in the blood. We plan to build a proteomic approach, which will combine our already established protein biomarkers

of ovarian cancer (i.e. OVA1, OVERA, OVA1plus) with genomic targets that characterize 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 foundational model for 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 intended as an aid to further assess the likelihood of malignancy in women with an ovarian adnexal mass for which surgery is planned when the physician's independent clinical and radiological evaluation does not indicate malignancy; (2) OVERA, a second-generation biomarker reflex intended to maintain OVA1's high sensitivity while improving specificity; (3) OVA1plus, a reflex offering which uses OVA1 as the primary test and OVERA as a confirmation for OVA1 intermediate range results and leverages the strengths of OVA1's MIA sensitivity and OVERA's (MIA2G) specificity and as a result reduces false elevations by over 40%; (4) Aspira GenetiX, a genetic test for hereditary gynecologic cancer risk, with a core focus on hereditary female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers; and (5) Aspira Synergy, our decentralized testing platform and cloud service for decentralized global access of both protein biomarker and hereditary genetic testing. We plan to make OVA1, OVERA, OVA1plus and Aspira GenetiX and future technology available through Aspira Synergy. Our OVA1 test received FDA *de novo* classification in September 2009. OVA1 comprises instruments, assays, reagents, and the OVACALC software, which includes a proprietary algorithm that produces a risk score. Our OVERA test, which includes an updated version of OVACALC, received FDA 510(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, 2021, our product and related services revenue has been limited to revenue generated by sales of OVA1, OVA1plus and Aspira GenetiX. In 2021, we entered into decentralized arrangements with large healthcare networks and large practices for our Aspira Synergy platform offering specialty and genetic testing solutions. The modules available under Aspira Synergy include our flagship OVA1plus risk assessment, Genetics Carrier Screening, and Genetics Hereditary Cancer solutions. The Company has entered into four technology transfer agreements since the launch of Aspira Synergy. The first two agreements are with two of the nation's largest and leading independent women's healthcare groups which together include approximately 750 providers and serve approximately 950,000 patients annually. The other two agreements are with independent laboratories providing services across five states. In the fourth quarter of 2021, we started receiving specimens related to our OVA1 Aspira Synergy product.

We are developing three additional products and related services, including two diagnostic algorithms, OVAWatch and EndoCheck, as well as 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.

OVAWatch has been developed and is validated for use in Aspira's CLIA-certified high complexity lab as a non-invasive risk assessment test for use in conjunction with clinical assessment and imaging to determine ovarian cancer risk for patients with an adnexal mass. OVAWatch is currently under market and scientific review. We plan to launch the OVAWatch test as an LDT in two stages. Phase I will be a single use point in time test, and Phase II will allow for serial monitoring. We will focus on advancing to the commercial phase of the OVAWatch launch plan including driving provider adoption during the second half of 2022. We believe the single-use product has the potential to triple the addressable market over OVA1plus our current ovarian cancer test. The launch of the serial monitoring test remains targeted for 2023 upon publication of data from the ongoing prospective serial monitoring clinical study.

EndoCheck, a non-invasive blood test to be used in conjunction with other non-surgical modalities, is designed to be an aid in the detection of endometriosis and address the patient population of women who are experiencing moderate to severe pelvic pain to provide non-invasive surgical confirmation that their symptoms are indicative of endometriosis. The goal of this test is to support an early diagnosis and direct appropriate medical management that potentially reduces the progression of disease. Current detection methods for endometriosis require surgery and a surgical biopsy diagnosis and/or visualization diagnosis. EndoCheck is intended to address this large patient population by using a non-invasive solution with both the sensitivity and specificity equal to or greater than surgical biopsy and/or visualization.

OVAInherit will be designed as a non-invasive 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 likelihood that a woman has an early-stage gynecological cancer that is not visible using traditional ultrasound methodologies, and thereby to aid in early diagnoses. Our OVAInherit related clinical studies, OVANex and OVA360, initiated in late 2019 and early 2020, respectively, are focused on developing data to support a diagnostic test for the early detection of ovarian cancer.

We ultimately plan to commercialize each of OVA1, OVERA, OVA1plus, Aspira GenetiX, OVAWatch, EndoCheck, OVAInherit and Aspira Synergy on a global level. We currently hold CE marks for OVA1 and OVERA. In addition, each of OVA1 and OVERA, and the reflex offering, OVA1plus, will be offered on our global testing platform, which will allow 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. The Centers for Medicare & Medicaid Services ("CMS") issued a supplier number to ASPiRA LABS in 2015.

Core Products

About OVA1 and OVERA: Our initial product, OVA1, is a blood test that is intended as an aid to further assess the likelihood of malignancy in women with an ovarian adnexal mass for which surgery is planned 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.

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. OVA1plus is also available through our decentralized platform structure, Aspira Synergy. This allows other facilities, including hospital networks and large physician practices, to perform OVA1plus tests using Aspira Synergy's cloud-based information and storage platform to 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. 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 included 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 March 2021, we launched the validated 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 solution from specimen collection to a customized white-label report for clinical laboratories to internalize testing of our products. The Aspira Synergy platform offers specialty and genetic testing solutions to empower health systems, physician groups and independent laboratories to conduct tests and receive results by using the Aspira Synergy platform. The Aspira Synergy platform offers three modules: the OVA1plus risk assessment module which includes two FDA-cleared tests (OVA1 and OVERA), the Genetics Carrier Screening module and the Genetics Hereditary Cancer module.

The Aspira Synergy OVA1plus solution launched in 2021 with our first fully deployed and implemented solution was with one of the largest women's health networks in the USA. The Aspira Synergy OVA1plus solution gives this women's health network and other clients the ability to perform OVA1plus tests using the Aspira Synergy platform to receive the OVA1plus risk assessment score, enabling increased reach and patient access. The deployment process of the Aspira Synergy Genetics client projects began in the first quarter of 2022.

The Aspira Synergy Genetics solution includes a fully validated Next Generation Sequencing ("NGS") assay. The Aspira Synergy Genetics solution 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 can be fully automated, providing limited wet lab and specimen analysis time, allowing clients to implement and run genetic testing at scale and with minimal cost, time and labor at accelerated turn-around times. In July 2021, Aspira was granted a CLIA Certificate of Accreditation for our laboratory at our Connecticut office, which has enabled us to support our Aspira Synergy platform. We expect the Aspira Synergy platform to expand our breadth and reach of access for all Aspira products, as we expect that every commercialized product, as well as pipeline innovations, will eventually be integrated into our Aspira Synergy platform.

Product Pipeline

About OVAWatch: The OVAWatch blood test is designed to support detecting the risk of malignancy in women with an adnexal 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 test was developed through a rigorous scientific and clinical-based process based on data from the New York State laboratory developed test and from our FDA regulatory process in 3,000 patients. The OVAWatch technology will be validated for this application in three separate cohorts of women. The first cohort will be patients with an identified pelvic mass and symptoms. The second cohort will be women whose pelvic mass is found incidentally and are asymptomatic, and that are also not scheduled for surgery. The third cohort will be 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. We will be launching the OVAWatch test as an LDT in two stages. Phase I will be a single use point in time test, and Phase II will allow for serial monitoring. We will focus on advancing to the commercial phase of the OVAWatch launch plan including driving provider adoption during the second half of 2022. We believe the single-use product has the potential to triple the addressable market over OVA1plus our current ovarian cancer test. The launch of the serial monitoring test remains targeted for 2023 upon publication of data from the ongoing prospective serial monitoring clinical study. The OVAWatch test is expected to have a high sensitivity and specificity as well as a high negative predictive value, which will allow physicians to serially monitor women with a mass to delay or avoid unnecessary surgery. A manuscript describing the initial analytical validation results was submitted to a peer-reviewed publication and was accepted on March 22, 2022.

About EndoCheck: The EndoCheck blood test is designed to be an aid in the diagnosis and detection of endometriosis. In the first quarter of 2021, we submitted to the FDA a Breakthrough Device designation request with respect to EndoCheck. The FDA's Breakthrough Devices Program provides patients and health care providers with timely access to medical devices, including in vitro diagnostic tests, which provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment and review. We had significant and productive dialogue with the FDA regarding our request, and the FDA has demonstrated interest in continuing to work with us on EndoCheck. Given the FDA's feedback, we anticipate continuing our discussions with the agency on Breakthrough Device Program designation as we develop the required performance data. There is no assurance that the FDA will grant our request for EndoCheck to be designated as a Breakthrough Device. If our device is granted a Breakthrough Device designation, we plan to move forward with FDA interaction through a variety of options including sprint discussions, a request for a discussion on a data development plan, and a request for clinical protocol agreement and confirmation that any final submission would be a *de novo* submission. In late October 2021, the FDA published updated guidance for the content of Premarket Submission for Software Contained in Medical Devices, specific to "Artificial Intelligence/Machine Learnings-Based Software as a Medical Device" which clarified the FDA's expectations and provided the framework for our future EndoCheck device. We are currently working to ensure our EndoCheck development process is aligned with the FDA's proposed framework. We plan to proceed on a parallel path with the Breakthrough Device process as well as with the LDT development process. This dual track approach pursues the commercialization of an EndoCheck LDT, whereby both clinical validity and real-world clinical utility data may be developed to support successful clinical adoption and reimbursement of the LDT while providing the data needed to demonstrate device performance for both a Breakthrough Designation decision and the subsequent FDA authorization required to market a device designated as "Breakthrough."

About OVAInherit: The OVAInherit blood test is designed to target a high-risk diagnostic test for those patients who are genetically predisposed or have family history of ovarian cancer. Studies have shown that in the general U.S. population 1 in 400 women have a high risk BRCA1/2 gene mutation. Among people of Ashkenazi Jewish descent, the prevalence is even greater and 1 in 40 have a high risk BRCA1/2 gene mutation. 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 two clinical trials, OVANex and OVA360, to evaluate our OVAInherit product. There is no definite timeline for the OVAInherit launch at this time.

Pipeline Expansion Strategy: We are focused on execution of the following ten core strategic business drivers in delivering state-of-the-art gynecologic health solutions starting with ovarian cancer diagnostics, and specialized laboratory services to build long-term value for our investors:

1) Maximizing the existing OVA1plus (OVA1 and OVERA, a next generation biomarker reflex, on the same platform) opportunity by actively pursuing payer coverage and government support to drive commercialization of OVA1plus, which we believe will deliver improved domestic market penetration and international expansion;
2) Leveraging our existing database and specimen bank while building our specimen and data repository of gynecologic pelvic mass patients;
3) 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; this may occur via licensing or other business development and merger and acquisition opportunities that represent synergistic offerings in women's health;
4) Coupling our OVA1 products with an individual's hereditary genetic risk to refine ovarian cancer risk assessment for high-risk populations; and
5) Establishing a proprietary decentralization platform, Aspira Synergy, to allow large healthcare networks and gynecologic practices to access OVA1plus technology algorithms and Aspira GenetiX algorithms as a technology transfer service, while also obtaining access to de-identified data through these arrangements to allow us to enhance our algorithm development on a cost-effective basis.

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

Studies and Publications

In parallel to building our OVA platform offering and our commercial deployment, we have been working on several key publications and product extensions.

On August 10, 2021, in a special ovarian cancer edition, Diagnostics published a paper entitled *"Salvaging Detection of Early-Stage Ovarian Malignancies When CA125 is Not Informative."* The paper reports that in a retrospective study of 2,305 patients, OVA1 detected over 50% of ovarian malignancies in premenopausal women that CA125 would have missed. OVA1 also correctly identified 63% of early-stage cancers missed by CA125. This paper further validates and supports OVA1's superior early-stage detection of ovarian cancer versus the current standard of care in a large population.

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 2021, Fortune Business Insight, a market research and business consulting partnership, published a study which forecasts the global *in vitro diagnostic* ("IVD") market to reach $149.03 billion by 2028, growing at a compound annual growth rate of 6.3% from 2021 to 2028. 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. Furthermore, an increasing number of women are becoming aware of the importance of early detection, particularly in gynecologic diseases.

Ovarian Cancer

Background

Commonly known as the "silent killer," ovarian cancer leads to nearly 13,000 deaths each year in the United States. As of early 2022, The American Cancer Society ("ACS") estimated that nearly 20,000 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 93%, 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 30.0%.

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 coupled with specialist medical centers improves outcomes for women with these tumors. Published guidelines from the Society of Gynecologic Oncology ("SGO") and the ACOG recommends 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 late-stage 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 menstruation, benign ovarian masses, liver disease, endometriosis, pelvic inflammatory disease, pregnancy and uterine fibroids.

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 regarding our OVA1-branded product "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 Ovarian Malignancy Algorithm ("ROMA") in African American women. [5],[6]

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

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

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

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

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

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

Commercialization and Distribution

Starting in 2014, we offered OVA1 via ASPiRA LABS. In March 2015, we entered into a commercial agreement with Quest Diagnostics. Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to 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.

Customers

In the United States, our clinical customer base can be segmented into four major groups: physicians (including women's care super-groups), physician office laboratories and national and regional laboratories. Both within and outside the United States, specimens are sent directly to us, and we bill either through payer contracts, client bill arrangements or a software subscription service via our 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 other "omics" 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, the University of Texas, M.D. Anderson Cancer Center and the Harvard Dana-Farber Cancer Institute, as well as through genetic testing providers such as Baylor Genetics. In addition, we actively seek collaborations and initiate dialog with clinical academics and other organizations, in order to generate publications, intellectual property or test development in broader areas of gynecologic oncology and other gynecologic diseases.

Our research and development efforts are detailed in the "Product Pipeline" section above.

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.

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.

Approximately 17,359 OVA1 tests were performed in 2021 compared to 13,557 in 2020. The increase is a result of expanded commercial efforts. In 2021, we continued to increase sales through Regional Account Managers and Directors. As awareness of our product continues to build, these representatives are focused on efforts that will have a positive impact on regional payers and create positive payer coverage decisions. They are working with local key opinion leaders and meeting with medical directors to discuss the clinical need, our technology solutions package and increasing patient 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 only sees about 2 to 4 patients per month who may need our OVA1plus 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 provider 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, 2021, Aspira's product and related services revenue has primarily been limited to revenue generated by sales of OVA1, with Aspira GenetiX generating minimal revenue throughout 2020 and 2021.

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 was scheduled to be in effect for a three-year term from January 2018 through December 2020. This rate is now extended through 2023. There are no assurances that reimbursement rates will not be changed after 2023.

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 2021, we announced 8 new contractual arrangements which brought the total number of covered lives to approximately 194 million as of December 31, 2021, representing 59% of the lives in the U.S.

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 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 Abbott Laboratories, Angle, Anixa, AOA, Becton Dickinson, Exact Sciences (Thrive), Grail 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 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 Ambry Genetics, Invitae Corporation, Laboratory Corporation of America, Inc., Myriad Genetics, Inc. and Natera offer similar genetic testing for hereditary cancer 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 20 issued United States patents, 9 pending United States patent applications and numerous pending patent applications and issued patents outside the United States. These patents and patent applications are directed to diagnostic technologies.

Manufacturing

We are the manufacturer of OVA1 and OVERA. The component assays of OVA1 and OVERA use purchased reagents. 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 relating 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

FDA Regulation of Medical Devices

In the U.S., medical devices, including IVD products, or IVDs, are subject to extensive regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices, including IVDs. IVDs are a type of medical device and include reagents and instruments used in the diagnosis or detection of diseases or conditions, including, without limitation, the presence of certain chemicals or other biomarkers. Predictive, prognostic, and screening tests can also be IVDs. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative and judicial sanctions, such as FDA refusal to approve pending pre-market approval applications ("PMAs"), issuance of warning letters or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject only to the general regulatory controls. Class II devices are moderate risk. They are subject to general controls and may also be subject to special controls. Class III devices are generally the highest risk devices. They are required to obtain premarket approval and comply with post-market conditions of approval in addition to general regulatory controls.

Generally, establishments that design and/or manufacture devices are required to register their establishments with the FDA. They also must provide the FDA with a list of the devices that they design and/or manufacture at their facilities.

The FDA enforces its requirements by market surveillance and periodic visits, both announced and unannounced, to inspect or re-inspect equipment, facilities, laboratories and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a Form 483, listing

instances where the manufacturer has failed to comply with applicable regulations and/or procedures or, if observed violations are sufficiently severe and urgent, a warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA make take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

cease and desist orders;
injunctions or consent decrees;
civil monetary penalties;
recall, detention or seizure of products;
operating restrictions or partial or total shutdown of production facilities;
refusal of or delay in granting requests for 510(k) clearance, de novo classification, or premarket approval of new products or modified products;
withdrawing 510(k) clearances, de novo classifications, or premarket approvals that are already granted;
refusal to grant export approval or export certificates for devices; and
criminal prosecution.

Pre-Market Authorization and Notification

While most Class I and some Class II devices may be marketed without prior FDA authorization, most other medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a PMA application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices; or (iii) authorized the device to be marketed through the *de novo* classification process, generally applicable for novel Class I or II devices. PMA applications, 510(k) premarket notifications, and *de novo* requests require payment of substantial user fees that are increased each fiscal year.

510(k) Premarket Notification

Product marketing in the U.S. for most Class II and a limited number of Class I devices typically follows the 510(k) premarket notification pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the "predicate device." A predicate device may be a previously 510(k) cleared device or a Class III device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for PMA applications, or a product previously placed in Class II or Class I through the *de novo* classification process. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

FDA has a user fee goal to apply no more than 90 calendar review days to 510(k) submissions. During the process, FDA may issue an Additional Information request, which stops the clock. The applicant has 180 days to respond. Therefore, the total review time could be up to 270 days.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval or *de novo* classification. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance for the modified device, the agency may retroactively require the manufacturer to seek 510(k) clearance, *de novo* classification, or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III regardless of the level of risk they pose. To avoid requiring PMA review of novel low- to moderate-risk devices classified in Class III by operation of law, Congress enacted a provision that allows the FDA to classify a novel low- to moderate-risk device into Class I or II in the absence of a predicate device that would support 510(k) clearance. The FDA evaluates the safety and effectiveness of devices submitted for review under the *de novo* pathway, and devices determined to be Class II through this pathway can serve as predicate devices for future 510(k) applicants. The *de novo* pathway can require clinical data.

FDA has a user fee goal to review a *de novo* request in 150 calendar review days. During the process, FDA may issue an Additional Information request, which stops the clock. The applicant has 180 days to respond. Therefore, the total review time could be as long as 330 days.

PMA Approval

A Class III product not eligible for either 510(k) clearance or *de novo* classification must follow the PMA approval pathway.

Results from adequate and well-controlled clinical trials are required for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all non-clinical, clinical, and other testing and information relating to the product's marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA.

The PMA approval process is generally more expensive, rigorous, lengthy, and uncertain than the 510(k) premarket notification process and *de novo* classification process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation ("QSR"), requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. FDA has a user fee goal to review a PMA in 180 calendar review days, if the submission does not require advisory committee input, or 320 review days if the submission does require advisory committee input. During the process, FDA may issue a major deficiency letter, which stops the review clock. The applicant has up to 180 days to respond. Therefore, the total review time could be up to 360 days, if the submission does not require advisory committee input, or 500 days if the submission does require advisory committee input.

If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials

Generally, at least one clinical trial is required to support a PMA application. Clinical studies also may be required for *de novo* classification or a 510(k) premarket notification. Clinical trials may also be conducted or continued to satisfy post-approval requirements for devices with PMAs. For significant risk investigational devices, the FDA regulations require that human clinical investigations conducted in the U.S. be approved under an investigational device exemption ("IDE"), which must become effective before clinical testing may commence. A nonsignificant risk investigational device does not require FDA approval of an IDE. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. If the FDA disapproves the IDE within this 30-day period, the clinical trial proposed in the IDE may not begin.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice ("GCP"), an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Clinical trials are typically conducted at geographically diverse clinical trial sites and are designed to permit the FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device when considering whether a device satisfies the statutory standard for commercialized. Clinical trials, for both significant and nonsignificant risk devices, must be approved by an institutional review board ("IRB"), an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with the FDA requirements or presents an unacceptable

risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions or sanctions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Post-Market Requirements

After a device is placed on the market, numerous general regulatory controls apply. These include: the QSR (which requires manufacturers to have a quality policy and procedures to ensure that devices are manufactured and records maintained in a prescribed manner with respect to manufacturing, testing, compliant handling, and record keeping), labeling regulations, the medical device reporting regulations (which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act). Failure to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction, can subject a manufacturer to warning letters, recalls, or other sanctions and penalties.

Advertising, marketing and promotional activities for devices are also subject to FDA oversight and must comply with the statutory standards of the FDC Act, and the FDA's implementing regulations. The FDA's oversight of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA also regulates industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context.

Manufacturers of medical devices are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses (i.e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for "off-label" uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off-label promotion. The failure to comply with prohibitions on "off-label" promotion can result in significant monetary penalties, revocation or suspension of a company's business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S. government that imposes significant administrative obligations and costs.

Violations of the FDC Act relating to the inappropriate promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

For a PMA or Class II 510(k) or *de novo* device, the FDA also may require post-marketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, quality-control, manufacture, packaging, and labeling procedures must continue to conform to the QSR after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with the QSR. The FDA may withdraw product approvals or recommend or require product recalls if a company fails to comply with regulatory requirements.

Clinical Laboratory Improvement Amendments of 1988

Clinical laboratories operating in or testing specimens from the U.S. are subject to CLIA, and related federal and state regulations, which provide for regulation of laboratory testing. Any customers using IVDs for clinical use in the United States will be regulated under CLIA, which establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. In particular, these regulations mandate that clinical laboratories must be certified by the federal government or a federally approved accreditation agency, or must be located in a state that has been deemed exempt from CLIA requirements because the state has in effect laws that provide for requirements equal to or more stringent than CLIA requirements. Moreover, these laboratories must meet quality assurance, quality control and personnel standards, and they must undergo proficiency testing and inspections. The CLIA standards applicable to clinical laboratories are

based on the complexity of the method of testing performed by the laboratory, as deemed by FDA, which range from "waived" to "moderate complexity" to "high complexity."

Laboratory-Developed Tests

The FDA considers LDTs to be tests that are designed, developed, validated and used within a single laboratory. 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 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 as of the date of this Form 10-K. Although FDA has generally exercised enforcement discretion for LDTs, the FDA retains discretion to require compliance with premarket or post-market requirements, such as when FDA deems it appropriate to address significant public health concerns.

At the beginning of the COVID-19 pandemic, FDA began requiring clinical laboratories offering LDTs for SARS-CoV-2 to obtain emergency use authorization ("EUA") before offering testing. In August 2020, the United States Department of Health and Human Services ("HHS") announced that FDA would no longer require premarket review of LDTs absent notice-and-comment rulemaking. In November 2021, HHS announced that this policy had been withdrawn, after which FDA resumed requiring submission of EUA requests for COVID-19 LDTs. FDA has not indicated an intent to regulate other, non-COVID, LDTs, which suggests that FDA's general policy of enforcement discretion remains in place.

Legislative proposals addressing the FDA's oversight of LDTs have been previously introduced. In March 2020, the Verifying Accurate, Leading-edge IVCT Development ("VALID"), Act of 2020 was introduced in the Senate, which proposes a regulatory framework for IVDs and LDTs and would require premarket approval for some in vitro clinical tests. The VALID Act was reintroduced in July 2021. 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. The VITAL Act was reintroduced in May 2021. Neither statute has been enacted.

As a manufacturer of IVDs, we are subject to regulatory oversight by the FDA under provisions of the FDC Act and regulations thereunder. We are required to register and list our products with the FDA and to comply with the QSR. We are required to submit a medical device report 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. As of the date of the filing of this Annual Report on Form 10-K, we have had zero complaints that required us to submit a medical device report to FDA. Additionally, we are subject to inspection by the FDA. Further, we are required to comply with FDA requirements for labeling and promotion.

Clinical studies of our IVD products, such as OVANex and OVA360, must be conducted in accordance with FDA's investigational device exemption regulations.

Our IVD devices also may require premarket authorization by FDA. OVA1, the first FDA-authorized blood test for the pre-operative assessment of ovarian masses, was authorized by the FDA in September 2009 under the *de novo* classification pathway. We received 510(k) clearance for OVERA, our second-generation biomarker panel, in March 2016.

We also may be required to conduct post-market surveillance of medical devices as a condition of granting marketing authorization. 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.

Our clinical laboratory activities are subject to CLIA and related state laws. In June 2014, we launched a clinical laboratory, ASPiRA LABS. ASPiRA LABS holds a CLIA Certificate of Accreditation and a state laboratory license or permit in California, Florida, Maryland, New York, Pennsylvania and Rhode Island. In July 2021, we were granted a CLIA Certificate of Accreditation for our laboratory at our Connecticut office. 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.

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, 2021, we had 106 full-time employees and 108 total employees. We generally engage independent contractors on a part-time basis from time to time.

Code of Ethics

We have adopted a Code of Ethics. 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, as well as its variants. If infection rates rise or if significant action is taken to contain the pandemic again in the future, we will likely experience similar impacts as we had in 2020 and 2021, which include test volume decreases, challenges for our sales force, including limiting the ability to make in-person sales calls, shortages of skilled labor, and difficulty recruiting participants in studies, and as a result, our business, results of operations and financial condition are likely to be adversely affected. To the extent our testing volumes decrease or we are unable to collect from patient payers, our revenues, cash flows from operations and liquidity will be adversely impacted. Although the impacts of COVID-19 on our business have lessened as compared to earlier periods of the pandemic, there is no assurance that sales or collections will return to normal levels during 2022 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 2022. 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 2020 and 2021 was 13,557 and 17,359, 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 may also adversely affect payers and result in a material change in coverage, adversely affecting our business, financial condition and results of operations.

We are responsible for obtaining payment from third-party payers. Accordingly, our future revenues will be dependent upon third-party reimbursement payments to ASPiRA LABS. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to change and particularly volatile during the early stages of commercialization. There remain questions as to what extent third-party payers, like Medicare, Medicaid and private insurance companies will provide coverage for OVA1, OVERA, OVA1plus, 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. Although the PAMA legislation allows for no more than a 15% fee reduction between 2021 and 2023, uncertainty regarding reimbursement rates could create payment uncertainty from other payers as well. The reimbursement rates for OVA1, OVERA, OVA1plus, OVAWatch, 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 variance 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 including increased use of Laboratory Benefits Management firms ("LBM's"). In addition, more payers are implementing pre-authorization requirements for our testing. These measures have resulted in reduced payment rates and decreased utilization of diagnostic tests such as OVA1 and OVERA.

Further, the trend among many payers is to limit the size of their lab networks, which is making it more difficult to secure preferred provider contracts for some services. 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, although PAMA has established specific dates by which they will make any changes. 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 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 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, two bills were introduced in the Senate: the Verifying Accurate, Leading-edge IVCT Development Act, or the VALID Act, which would expressly grant FDA authority to regulate LDTs under a risk-based framework; and the Verified Innovative Testing in American Laboratories Act, or the VITAL Act, which would assign LDTs to regulation solely under CLIA and would direct CMS to update its CLIA regulations. Both the VALID Act and the VITAL Act were reintroduced in 2021. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business. In the meantime, the regulation by the FDA of LDTs remains uncertain.

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. In November 2021, HHS announced that this policy had been withdrawn after which the FDA resumed requiring submission of emergency use authorization ("EUA") requests, for COVID-19 LDTs. The FDA has not indicated an intent to regulate other, non-COVID, LDTs, which suggests that the FDA's general policy of enforcement discretion remains in place. However, the FDA may, in the future, seek to actively regulate non-COVID LDTs, or Congress may act to provide further direction on the regulation of LDTs and substantially modify the regulation of IVDs.

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.

In the first quarter of 2021, we submitted to the FDA a Breakthrough Device designation request with respect to EndoCheck. While the FDA has demonstrated interest in continuing to work with us on EndoCheck, and while we plan to continue our discussions with the agency on Breakthrough Device Program designation, there is no assurance that the FDA will grant our request for EndoCheck to be designated as a Breakthrough Device.

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 demonstrate clinical validity in larger clinical studies or may not achieve acceptable levels of analytical 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 OVAWatch 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, legislators, payers, 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 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. ROMA is a competitive test with OVA1, OVERA and OVA1plus that has adversely impacted and may continue to materially adversely impact our revenue. In addition, competitors, Becton Dickinson, Abbott Laboratories, AOA, Exact Sciences (Thrive), Grail, Anixa, Angle, 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 safety and 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 FDC 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 FDC 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, *de novo* classification, 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 a 510(k) submission, *de novo* classification 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 ensure that any necessary 510(k) clearance, *de novo* classification, or PMA will be granted on a timely basis, or at all. To the extent we seek FDA 510(k) clearance, *de novo* classification or FDA pre-market approval for other diagnostic tests, any delay by or failure of the FDA to clear, classify, 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 granted the request for *de novo* classification for OVA1 in September 2009 and cleared OVERA in March 2016. 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 QSR requirements, which establish extensive requirements for quality assurance and control as well as manufacturing procedures. Failure to comply with these regulations could result in enforcement actions for us or our potential suppliers. Adverse FDA actions in any of these areas could significantly increase our expenses and reduce our revenue. We will need to undertake steps to maintain our operations in line with the FDA's QSR requirements. Some components of OVA1 and OVERA are manufactured by other companies and we are required to ensure that, to the extent that we incorporate those components into our finished OVA1 and OVERA products (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, fail to supply stock due to supply shortages, 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, OVERA and OVA1plus.

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 meet our specifications and 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 of a revised OVA1, OVERA or OVA1plus design. Likewise, discontinuation or failure to support or service the instruments may pose risk to ongoing operations.

Changes in healthcare policy could increase our costs and adversely impact sales of and reimbursement for our tests, which would have an adverse effect on our business, financial condition and results of operations.

PAMA established a Medicare reimbursement system for clinical laboratories beginning in 2018 that is based on rates paid to laboratories by private payers. The CMS also issued various regulations and guidance to implement PAMA that require certain laboratories to report information the rates private payers pay them for laboratory tests, including Multianalyte Assays with Algorithmic Analyses. In addition to these changes, a number of states are also contemplating significant reform of their healthcare reimbursement 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, in Texas. 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 is a federal law that 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. A few states, including New York State may require that additional quality standards be met and that detailed review of scientific validations and technical procedures for tests occur. In the future, the federal government may change the way that clinical laboratory tests are regulated, which may adversely affect our business, financial condition and results of operations.

ASPiRA LABS holds a CLIA Certificate of Accreditation and a state laboratory license or permit in California, 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 also may impose the following alternative sanctions: (a) directed plan of correction, (b) state onsite monitoring, and/or (c) civil monetary penalty. In addition, the government 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 hazard 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, the Eliminating Kickbacks in Recovery Act ("EKRA"), 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;
the federal fraud, waste and abuse laws 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.

In 2020, Congress passed the Consolidated Appropriations Act and included a section called the "No Surprises Act." The No Surprises Act prohibits a health care provider from billing a commercially insured patient more than in-network cost-sharing amounts when a service originated from an in-network hospital or ambulatory surgery center, even if the provider is out-of-network with the patient's health plan. It also requires a provider to provide a good faith estimate of expected charges to an uninsured or self-pay patient upon the patient's request or when a patient schedules a service. Several states have similar laws that aim to protect patients from unexpected health care charges. Civil penalties of up to $10,000 per occurrence can be imposed for

knowing violations of the No Surprises Act that are not remediated within a certain timeframe, and states may impose their own penalties for violations of their surprise billing laws.

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, 2021 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 2022 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 2022 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 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 allegations of 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 filed on July 6, 2020, December 30, 2021, January 13, 2022, February 14, 2022 and February 16, 2022, we estimate that a total of five persons beneficially own approximately 47.98% of our outstanding common stock. Under the May 2013 stockholders agreement, two of our stockholders 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, 2021, the closing trading price of our common stock ranged from a high of $9.13 per share to a low of $1.63 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 issuance of common stock in public or private equity offerings, debt financings, collaborations, licensing arrangements, grants and government funding and strategic alliances. As discussed in "Risks Related to our Business and Industry," our management believes the successful achievement of our business objectives will require additional financing through one of these avenues. 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 18, 2022, we had 112,138,741 shares of our common stock outstanding and 3,729,204 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 10,257,908 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. To continue our commercialization objectives and reach our financial and operational goals, we require skilled sales individuals with familiarity in our industry. We have from time to time experienced, and may in the future experience, shortages of certain types of qualified employees.

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 have and may continue to experience turnover in certain executive officer and key employee roles.

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, cyber-attacks, 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 be increasingly 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 invested and continue to invest in disaster recovery plans, security initiatives, and risk management in line with applicable regulations and industry standards, they might not adequately protect us in the event of a system failure, cyber-attack, cyber-breach, data breach or other adverse event. 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 by or against us could be costly and time-consuming to prosecute or 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.

Location	Approximate Square Feet	Primary Functions	Lease Expiration Date
Austin, Texas	4,218 sq. ft.	ASPiRA LABS facility, research and development, clinical and regulatory and administrative offices	January 31, 2023
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 18, 2022, there were 81 registered holders of record of our common stock. The closing price of our common stock on March 18, 2022 was $1.19.

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, 2021, options to purchase 4,366,311 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, 2021, options to purchase 5,891,597 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, 2021, were as follows:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Shares Reflected in First Column)
Equity compensation plans approved by security holders	10,257,908	$ 2.96	3,729,204
Equity compensation plans not approved by security holders	-	-	-
Total	10,257,908		3,729,204

Performance Graph

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

ITEM 6. [Reserved]

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-21 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 eradicate late-stage detection of ovarian cancer and to ensure that our solutions will meet the needs of women of all ages, races, ethnicities and stages of the disease. Our core patient goal is to develop a lifelong relationship with each patient, ensuring each woman has access to best-in-class diagnostics.

Our plan is to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological diseases. We plan to continue commercializing our new generation of technology as well as distribute our technology through our decentralized technology transfer service platform, known as "Aspira Synergy". We also intend to raise public awareness regarding the diagnostic superiority of OVA1 as compared to cancer antigen 125 ("CA125") for all women, but especially for Black women with adnexal masses, as well as the importance of machine learning algorithm development in ethnic populations. We also plan to advocate for legislation and professional society guidelines to provide broad access for our products and services.

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 salesforce, and in 2021, we put OVA1 on our global testing platform, Aspira Synergy. This platform allows tests to be deployed internationally as well as run by clients in the United States at major customer sites. In 2022, we plan to continue our efforts to commercialize OVA1plus by utilizing select partnerships for distribution, expand our managed care coverage and contracts in select markets, grow our sales force, increase adoption in our existing customer base, and further deploy of our Aspira Synergy technology transfer platform. We also plan to develop a LDT 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. In 2021, we expanded access to our tests among Medicaid patients as part of our corporate mission to make the best care available to all women. Our first LDT algorithm, branded as OVAWatch, focuses on monitoring women with pelvic masses. We plan to launch the OVAWatch test as an LDT in two stages. Phase I will be a single use point in time test, and Phase II will allow for serial monitoring. We will focus on advancing to the commercial phase of the OVAWatch launch plan including driving provider adoption during the second half of 2022. We believe the single-use product has the potential to triple the addressable market over OVA1plus our current ovarian cancer test. The launch of the serial monitoring test remains targeted for 2023 upon publication of data from the ongoing prospective serial monitoring clinical study. We expect that our second diagnostic algorithm, EndoCheck, will be an aid in the diagnosis of endometriosis. We also plan to expand our portfolio of products to include OVAInherit, which aims to identify risk of malignancy in 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, making our non-invasive blood biopsy more efficient and patient friendly.

To continue our commercialization objectives and reach our financial and operational goals, we require skilled sales individuals with familiarity in our industry. We have from time to time experienced, including as a result of labor shortages during the COVID-19 pandemic, and may in the future experience, shortages of certain types of qualified employees.

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.

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

On October 30, 2021, Sandra Brooks, M.D., M.B.A., a director of the Company's board of directors, resigned from the Company's board of directors for personal reasons.

Effective February 23, 2022, the independent directors of the Company's board of directors appointed James T. LaFrance as Lead Independent Director, effective as of March 1, 2022, and the Company's board of directors appointed Celeste Fralick, Ph.D. to the Company's board of directors and its Audit Committee.

Also, on February 23, 2022, the Company's board of directors appointed Valerie B. Palmieri as its Executive Chair, effective as of March 1, 2022 and appointed Nicole Sandford, a current director on the board of directors, as the Company's President and Chief Executive Officer, each effective as of March 1, 2022.

On February 23, 2022, the Company's board of directors appointed James T. LaFrance as Audit Committee Chair, effective as of March 1, 2022

Business, Product and Coverage Updates

Government Strategy Updates

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.

In the first quarter of 2021, we submitted to the FDA a Breakthrough Device designation request with respect to EndoCheck. The FDA's Breakthrough Devices Program provides patients and health care providers with timely access to medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment and review. We have been in communications with the FDA regarding our request, and the FDA has demonstrated interest in continuing to work with us on EndoCheck, and we plan to continue our discussions with the agency on Breakthrough Device Program designation. There is no assurance that the FDA will grant our request for EndoCheck to be designated as a Breakthrough Device. If our device is granted a Breakthrough Device designation, we plan to move forward with interacting with the FDA through a variety of options including sprint discussions, a request for a discussion on a data development plan, and a request for clinical protocol agreement, and any final submission will be a *de novo* submission. As of late October 2021, the FDA's Center for Devices and Radiological Health issued an updated guidance for the content of Premarket Submission for Software Contained in Medical Devices, specific to "Artificial Intelligence/Machine Learnings-Based Software as a Medical Device Action Plan" which will provide a much-needed framework for our future EndoCheck devices. We are currently working to ensure our EndoCheck development process is aligned with the proposed framework. We plan to proceed on a parallel path with the Breakthrough Device process as well as with the LDT development process. This dual track approach pursues the commercialization of an EndoCheck LDT, whereby real-world clinical validity data will be developed that also will support the data needed for an FDA marketing authorization, subsequent to FDA's Breakthrough designation decision.

On September 27, 2021, we participated in a Congressional Briefing to discuss the gaps in ovarian health diagnostics and treatments as well as solutions to successfully address them. Immediate and innovative actions regarding education, research investment, detection, and insurance coverage were highlighted, in addition to the dire consequences of racial and ethnic disparities and inequities endemic to this malignancy.

Coverage Updates

On January 28, 2021, we announced that we had become a participating laboratory network provider for all Pennsylvania and West Virginia commercial health insurance products of Highmark.

On March 15, 2021, we announced coverage by New York State Medicaid – one of the larger Medicaid populations in the U.S., covering an estimated 6.5 million lives in the state.

On May 13, 2021, we announced the execution of an Aspira Synergy agreement with one of the largest women's health networks whereby the OVA1plus testing will be performed in its laboratory with data interpretation by Aspira. The health network employs over 300 physicians and is responsible for 500,000 patient visits per year.

On July 8, 2021, the Company announced that AIM Specialty Health, which represents more than 50 million lives in the United States, one of the nation's largest Laboratory Benefits Management firms owned by Anthem Blue Cross Blue Shield, published guidelines indicating that OVA1 is considered medically necessary per the test's FDA-cleared label. This allows all Anthem and other BCBS plans to modify their own OVA1 coverage policies to reflect this coverage.

On January 31, 2022, we announced that we entered into agreements to provide our testing services to Medicaid plan members in the state of New Hampshire and Washington, D.C equaling nearly a half million covered lives. The state of New Hampshire covers 200,000 lives and Washington D.C. covers 265,000 lives under their respective Medicaid programs. With the addition of these plans, Aspira is now credentialed to provide its OVA1 testing to nearly 80% of the Medicaid population in the U.S., totaling approximately 60 million lives.

Abstract / Study Updates

On May 13, 2021, we announced the initiation of a large prospective study with The Feinstein Institutes for Medical Research, the science arm of Northwell Health, the largest private healthcare provider in New York State. Northwell Health treats over 2 million patients annually and employs over 16,000 credentialled physicians. The study will further support longitudinal studies for the use of OVAWatch as a serial monitoring test for high-risk women predisposed for hereditary ovarian cancer.

In June 2021, we presented an abstract for the American Society for Clinical Oncology 2021 conference and then subsequently submitted the full analytical validation for publication in the third quarter of 2021, which is currently pending acceptance. We plan to publish the clinical validation in late 2022 or early 2023, once the prospective clinical trial has closed and the data has been analysed.

Collaboration Updates

On March 25, 2021, we announced that we entered into an agreement with Harvard Dana-Farber Cancer Institute , Brigham and Women's Hospital and Medical University of 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 ovarian cancer.

On June 25, 2021, ObsEva S.A. entered into an agreement with the Company to provide certain serum samples to be used in clinical trials. The Company plans to use the samples in its EndoCheck product validation trial.

On October 7, 2021, we announced a partnership with Genoox Ltd., the world's largest community-driven genomic data platform, to develop solutions to advance women's health with rapid results, diagnosis, and insights. Currently, the majority of genetic sequencing information can be found across multiple databases which can limit the ability for medical professionals to access and analyze this important data. Without advanced data aggregation and analytics that inform machine learning and artificial intelligence algorithms, it is more difficult to detect early-stage diseases as well as monitor and treat patients effectively. Genoox's global platform brings together onto a single platform information available in the public domain, allowing for the complete analysis of the data and better patient care. We plan to leverage this knowledge base to expand on our proprietary algorithm development across multiple product lines.

We expect our collaboration work with Harvard Dana-Farber Cancer Institute and Medical University of Lodz Phase 1 Proof of Concept to continue to be successful. The Phase 1 evaluation surpassed all required metrics and based on the outcome data, the Aspira innovation team along with the collaborators from the aforementioned institutions have begun implementing Phase 2 of the study. In Phase 2, the team is evaluating the combined potential impact of our protein biomarker algorithms and the investigators' miRNA technology in the development of this assay and platform, which we refer to as OVAInherit.

In connection with our Strategic Research Collaboration Agreement for the development and commercialization of a Micro RNA high risk ovarian cancer early-detection test with Dana-Farber Cancer Institute, Brigham and Women's Hospital and Medical University of Lodz, during March 2022, we exercised the option for an exclusive world-wide license of this cutting-edge miRNA technology and plans to continue development of a novel combined assay utilizing a new platform with our collaborators.

During the first quarter of 2022, we executed a reorganization and strategic refresh resulting in the separation of a number of employees. The changes were aimed at enhancing our national sales force and driving the accelerated adoption of OVA1plus as the standard of care for early risk detection of ovarian cancer in women who have been planned for surgery. The organizational changes will result in the recording of one-time severance, separation, and settlement payments as well as legal costs in the first quarter of approximately $1,258,000 including estimated future payouts, partially offset by insurance reimbursement of $523,000.

On January 5, 2022, we announced that we entered into a commercial enterprise agreement with Axia Women's Health, one of the nation's largest and leading independent women's healthcare groups. Axia Women's Health is an innovative and progressive community of more than 400 providers and 150 women's health centers across New Jersey, Pennsylvania, Indiana, Ohio, and Kentucky. Axia Women's Health providers offer services across the care continuum including obstetrics, gynecology, mammography, urogynecology, fertility, and other sub-specialties.

COVID-19 Pandemic

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. Our commercial efforts to enter into decentralized arrangements with large healthcare networks and supergroups have continued to move forward. Additionally, as a result of the COVID-19 pandemic and actions taken to contain it, our test volume, and resulting revenue, decreased significantly through the beginning of the third quarter of 2020. Volumes started trending back to pre-COVID levels during the late third quarter of 2020. However as various COVID-19 variants evolved, we experienced fluctuating testing volumes. In order to reduce the impact of limitations on visiting physician offices due to closures and quarantines, we implemented other mechanisms for reaching physicians such as virtual sales representative meetings, Key Opinion Leader presentations, and increased digital sales and marketing. Patient enrollment for our planned clinical research studies has been slower than originally planned due to the impact of clinic closures and patients not seeking medical care in some states, which has led to delays in the completion of such studies.

As a result of the COVID-19 pandemic and actions taken to contain it, the majority of our non-laboratory employees had been working remotely since March 2020. In the third quarter of 2021, non-laboratory employees returned to the office on a hybrid schedule for two to three days per week. We expect to continue to have a hybrid working schedule for non-laboratory employees. 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 two 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.

In the fourth quarter of 2021, our test volume increased by 10% compared to the third quarter of 2021. Although we experienced an increase in volume, we believe 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 the filing of this Form 10-K. The full impact of the COVID-19 pandemic continues to evolve as of the date of the filing of this Annual Report on Form 10-K.

Results of Operations – Year Ended December 31, 2021 as compared to Year Ended December 31, 2020

The Company's selected summary financial and operating data for the years ended December 31, 2021 and 2020 were as follows:

	Year Ended December 31,		Increase (Decrease)	
(dollars in thousands)	2021	2020	Amount	%
Revenue:				
Product	$ 6,568	$ 4,543	$ 2,025	45
Genetics	244	108	136	126
Total revenue	6,812	4,651	2,161	46
Cost of revenue:				
Product	3,016	2,517	499	20
Genetics	734	898	(164)	(18)
Total cost of revenue	3,750	3,415	335	10
Gross profit	3,062	1,236	1,826	148
Operating expenses:				
Research and development	5,314	2,104	3,210	153
Sales and marketing	17,086	8,843	8,243	93
General and administrative	13,257	8,270	4,987	60
Total operating expenses	35,657	19,217	16,440	86
Loss from operations	(32,595)	(17,981)	(14,614)	81
Interest income (expense), net	(48)	10	(58)	(580)
Other income, net	981	66	915	1,386
Net loss	$ (31,662)	$ (17,905)	$ (13,757)	77

Product Revenue. Product revenue was $6,568,000 for the year ended December 31, 2021, compared to $4,543,000 for the same period in 2020. 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 45% product revenue increase is due to an increase in OVA1 test volume compared to the prior year, in addition to a higher average revenue per test, which increased from $334 in 2020 to $378 in 2021. This increase contributed to the total gross profit margin increasing from 26.6% in 2020 to 45.0% in 2021. We expect revenue to continue to improve in 2022 due to test volumes exceeding 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 28% to approximately 17,359 OVA1plus tests during the year ended December 31, 2021 compared to approximately 13,557 OVA1plus tests for the same period in 2020. The volume increase was primarily due to our commercialization investment, partially offset by decreases in test volume during certain periods of 2021 as a result of the COVID-19 pandemic and efforts to contain it.

The revenue per OVA1plus test performed increased from approximately $334 in 2020 to approximately $378 in 2021. This increase was primarily driven by increased volume of tests performed for higher revenue-per-test-performed payers, such as those for Medicare and insurance carriers, along with decreased volume of tests performed for lower revenue-per-test-performed payers, such as 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 $244,000 for the year ended December 31, 2021, compared to $108,000 for the same period in 2020. Revenue for Aspira GenetiX is recognized when the Aspira GenetiX test is completed based on estimates of what we expect to ultimately realize. The 126% genetics revenue increase is primarily due to an increase in Aspira GenetiX test volume, as well as a higher revenue per test. We expect revenue to improve in 2022 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 64% to approximately 505 Aspira GenetiX tests during the year ended December 31, 2021 compared to approximately 307 Aspira GenetiX tests for the same period in 2020. The volume increase was primarily due to our commercialization investment, partially offset by decreases in test volume during certain periods of 2021 as a result of the COVID-19 pandemic and efforts to contain it.

Cost of Revenue - Product. Cost of product revenue was $3,016,000 for the year ended December 31, 2021 compared to $2,517,000 for the same period in 2020, representing an increase of $499,000, or 20%, 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 Aspira GenetiX revenue, which consisted primarily of personnel costs, consulting and licensing expenses was $734,000 for the year ended December 31, 2021 compared to $898,000 for the same period in 2020, representing a decrease of $164,000, or 18%, due primarily to one-time costs related to transitioning of outsourced genetics testing services in 2020 of $250,000.

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, 2021 increased by $3,210,000, or 153%, compared to the same period in 2020. This increase was primarily due to clinical validity and product development costs related to OVAWatch, our third-generation product, as well as investments in Aspira Synergy and consulting expenses associated with EndoCheck regulatory clearance. We expect research and development expenses to moderately increase in 2022, 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. 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, 2021 increased by $8,243,000, or 93%, compared to the same period in 2020. This increase was primarily due to increased personnel, recruiting costs, consulting costs, commissions, and promotional marketing expense. We expect sales and marketing expenses to moderately increase in 2022, due to investing in key strategic hires and product portfolio expansion.

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, 2021 increased by $4,987,000, or 60%, compared to the same period in 2020. This increase was primarily due to increased personnel expenses of $1,725,000, consulting expenses of $766,000, legal expenses of $961,000, recruiting expenses of $374,000, stock compensation expenses of $750,000, as well as director and officer insurance expenses of $288,000. We expect general and administrative expenses to increase slightly in 2022.

Interest Income (Expense, net). The Company had interest income of $10,000 for the year ended December 31, 2020 and $48,000 in interest expense for the year ended December 31, 2021. The change in the net balance from interest income to interest expense was primarily due to an increase in the loan contemplated under the DECD Loan Agreement (as defined below) and corresponding additional interest expense.

Other Income, net. Other income for the year ended December 31, 2021 increased by $915,000, compared to the same period in 2020, which consists primarily of forgiveness during the second quarter of 2021 of the Paycheck Protection Program loan (the "PPP Loan"), which the company obtained from BBVA USA in the aggregate amount of approximately $1,006,000 in May 2020.

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.

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 $471,728,000 as of December 31, 2021. The Company also expects to incur a net loss and negative cash flows from operations for 2022.

As discussed in Note 6 to the consolidated financial statements, in March 2016, the Company entered into a loan agreement (as amended on March 7, 2018 and April 3, 2020, the "DECD 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 DECD Loan Agreement. On December 3, 2020, the Company received a disbursement of the remaining $2,000,000 under the DECD Loan Agreement, as the Company had achieved the target employment milestone necessary to receive an additional $1,000,000 under the DECD Loan Agreement and the DECD determined to fund the remaining $1,000,000 under the DECD 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 DECD 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 do 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 3 of our consolidated financial statements.

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 to the consolidated financial statements, on May 1, 2020, the Company obtained the PPP Loan from BBVA USA in the aggregate amount of approximately $1,006,000. The application for these funds required the Company to certify, in good faith, 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 Loan, all or a portion of the principal amount of the PPP Loan was 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 used 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, was set to mature on May 1, 2022. The Company applied for forgiveness of the PPP Loan in March 2021, and, effective May 27, 2021, the SBA confirmed the waiver of the Company's repayment of the PPP Loan. The Company recognized a gain on forgiveness of debt of approximately $1,006,000 and reduced long- and short-term indebtedness by the same amount. The Company remains subject to an audit of the PPP loan. There is no assurance that the Company will not be required to repay all or a portion of the PPP Loan as a result of the audit.

As discussed in Note 7 to the consolidated financial statements, during June 2020, all of the 2,810,338 warrants from the Company's 2017 private placement were exercised. The Company received $5,060,000 in aggregate proceeds from the exercise of the warrants.

As discussed in Note 7 to the consolidated financial statements, on July 20, 2020, the Company completed a private placement of 3,150,000 Aspira common stock, par value $0.001 per share, for net proceeds of $10,641,000, after deducting expenses related to the private placement.

As discussed in Note 7 to the consolidated financial statements, on February 8, 2021, the Company completed a public offering (the "2021 Offering") resulting in net proceeds of approximately $47,858,000, after deducting underwriting discounts and offering expenses.

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.

As mentioned, the Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2021 we had an accumulated deficit of $471,728,000 and stockholders' equity of $30,172,000. As of December 31, 2021, we had $37,180,000 of cash and cash equivalents, and $7,840,000 of current liabilities. Working capital was $32,165,000 at December 31, 2021. 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 revenue from our products to be our only material, recurring source of cash in 2022. In the event that the Company's existing cash on hand is not sufficient to fund operations, meet its capital requirements or satisfy the anticipated obligations as they become due, the Company expects to take further action to protect its liquidity position. Such actions may include, but are not limited to:

Raising capital through an equity offering either in the public markets or via a private placement offering (however, no assurance can be given that capital will be available on acceptable terms, or at all);
Reducing executive bonuses or replacing cash compensation with equity grants;
Reducing professional services and consulting fees and eliminating non-critical projects;
Reducing travel and entertainment expenses; and
Reducing, eliminating or deferring discretionary marketing programs.

We expect to incur a net loss and negative cash flows from operations in 2022. The impact of the COVID-19 pandemic and actions taken to contain it on our liquidity for 2022 cannot be estimated as of the date of this filing.

However, we believe that our cash and cash equivalents 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 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 $27,395,000 for the year ended December 31, 2021, resulting primarily from the net loss reported of $31,662,000, which includes forgiveness of the PPP Loan in the amount of approximately $1,006,000, primarily offset by non-cash expenses in the amount of $3,539,000 related to stock compensation expense and $302,000 related to depreciation and amortization, and offset by changes in accounts payable, accrued and other liabilities of $2,248,000.

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, primarily offset by changes in accounts payable, accrued and other liabilities of $1,594,000.

Net cash used in investing activities was $184,000 and $490,000 for the years ended December 31, 2021 and 2020, respectively, which consisted primarily of property and equipment purchases.

Net cash provided by financing activities was $48,378,000 for the year ended December 31, 2021, which resulted primarily from the 2021 Offering, resulting in net proceeds to the Company of approximately $47,858,000, after deducting underwriting discounts and offering expenses. Net cash provided by financing activities was $20,152,000 for the year ended December 31, 2020, which resulted primarily from the proceeds from the PPP Loan of approximately $1,006,000 in May 2020, the proceeds from the exercise of the stock options of $1,637,000 in June 2020, the proceeds from the exercise of warrants of approximately $5,060,000 in June 2020, the proceeds from the private placement of approximately $10,641,000 in July 2020, after deducting expenses related to the private placement, and the proceeds from the DECD loan of $2,000,000 in December 2020.

We have significant NOL carryforwards as of December 31, 2021 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 2022 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 2022 through 2037 if not utilized. Our ability to use our NOLs during this period will be dependent on our 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.

Our management believes that Section 382 ownership changes occurred as a result of our follow-on public offerings in 2011, 2013 and 2015. Any limitation may result in the expiration of a portion of the 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 our valuation allowance. Due to the existence of a valuation allowance, it is not expected that such limitations, if any, will have an impact on our results of operations or financial position.

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, 2021 and 2020, consolidated statements of operations for the years ended December 31, 2021 and 2020, consolidated statements of changes in stockholders' equity for the years ended December 31, 2021 and 2020, consolidated statements of cash flows for the years ended December 31, 2021 and 2020 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, 2021.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2021, 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, 2021. 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, 2021 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, 2021, 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

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding our directors, committees of our Board of Directors, our director nomination process, and our executive officers appearing under the heading "Election of Directors," "Corporate Governance," "Management", "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 2022 (the "2022 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 2022 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 2022 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 2022 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" of the 2022 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-21.

(b) EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date	Filed 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	Amended and Restated Bylaws of Aspira Women's Health Inc., effective February 23, 2022	8-K	001-34810	3.1	February 28, 2022	
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 Master, LP, Jack W. Schuler and other purchasers named therein	8-K	001-34810	10.2	May 14, 2013	
4.4	Amended and Restated Promissory Note #1 by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective April 3, 2020	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 2010 Stock Incentive Plan (as amended effective June 21, 2018) #	8-K	001-34810	10.1	June 27, 2018	
10.7	Form of Vermillion, Inc.'s Stock Option Award #	10-K	001-34810	10.7	March 28, 2019	
10.8	Form of Vermillion, Inc.'s Restricted Stock Award #	10-K	001-34810	10.8	March 28, 2019	
10.9	Vermillion, Inc. 2019 Stock Incentive Plan #	8-K	001-34810	10.1	June 24, 2019	
10.11	Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Valerie B. Palmieri, effective March 1, 2022 #	8-K	001-34810	10.1	February 28, 2022	
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 and Services Agreement between 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	
10.21	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	Employment Agreement between Vermillion, Inc. and Robert Beechey dated December 18, 2017 #	8-K	001-34810	10.1	December 20, 2017	
10.24	Promissory Note, dated May 1, 2020, between Vermillion, Inc. and BBVA USA	8-K	001-34810	10.1	May 7, 2020	
10.25	Consulting Agreement, dated March 25, 2021, by and between David Schreiber and Aspira Women's Health Inc. #	10-Q	001-34810	10.1	May 14, 2021	
10.26	Employment Agreement between Aspira Women's Health Inc. and Nicole Sandford effective March 1, 2022 #	8-K	001-34810	10.2	February 28, 2022	
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					√
32.1	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 pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL")					
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

√ 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, 2021 and 2020, 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, 2021 and 2020, 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 the 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, 2021 was $6.6 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 or 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.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.
Austin, Texas
March 31, 2022

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 37,180	$ 16,631
Accounts receivable	1,027	865
Prepaid expenses and other current assets	1,624	1,077
Inventories	174	30
Total current assets	40,005	18,603
Property and equipment, net	464	583
Right-of-use assets	346	406
Restricted cash	250	-
Other assets	14	13
Total assets	$ 41,079	$ 19,605
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,501	$ 1,103
Accrued liabilities	5,299	3,618
Current portion of long-term debt	201	645
Short-term debt	779	611
Lease liability	60	23
Total current liabilities	7,840	6,000
Non-current liabilities:		
Long-term debt	2,718	3,477
Lease liability	349	409
Total liabilities	10,907	9,886
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at December 31, 2021 and December 31, 2020; 112,138,741 and 104,619,876 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	112	105
Additional paid-in capital	501,788	449,680
Accumulated deficit	(471,728)	(440,066)
Total stockholders' equity	30,172	9,719
Total liabilities and stockholders' equity	$ 41,079	$ 19,605

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,	
	2021	2020
Revenue:		
Product	$ 6,568	$ 4,543
Genetics	244	108
Total revenue	6,812	4,651
Cost of revenue[1]:		
Product	3,016	2,517
Genetics	734	898
Total cost of revenue	3,750	3,415
Gross profit	3,062	1,236
Operating expenses:		
Research and development[2]	5,314	2,104
Sales and marketing[3]	17,086	8,843
General and administrative[4]	13,257	8,270
Total operating expenses	35,657	19,217
Loss from operations	(32,595)	(17,981)
Interest income (expense), net	(48)	10
Other income, net	981	66
Net loss	$ (31,662)	$ (17,905)
Net loss per share - basic and diluted	$ (0.28)	$ (0.18)
Weighted average common shares used to compute basic and diluted net loss per common share	111,210,614	100,723,303
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:		
(1) Cost of revenue	$ 161	$ 106
(2) Research and development	311	34
(3) Sales and marketing	1,132	228
(4) General and administrative	1,935	1,180

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)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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-based compensation expense	-	-	1,366	-	1,366
Balance at December 31, 2020	104,619,876	$ 105	$ 449,680	$ (440,066)	$ 9,719
Net loss	-	-	-	(31,662)	(31,662)
Common stock issued in conjunction with exercise of stock options	557,566	-	718	-	718
Common stock issued in conjunction with public offering, net of issuance costs	6,900,000	7	47,851	-	47,858
Common stock issued for restricted stock awards	61,299	-	455	-	455
Stock-based compensation expense	-	-	3,084	-	3,084
Balance at December 31, 2021	112,138,741	$ 112	$ 501,788	$ (471,728)	$ 30,172

See accompanying Notes to Consolidated Financial Statements

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

	Twelve Months Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (31,662)	$ (17,905)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	37	26
Depreciation and amortization	302	265
Stock-based compensation expense	3,539	1,548
Loss on sale and disposal of property and equipment	1	3
Forgiveness of PPP loan	(1,006)	-
Changes in operating assets and liabilities:		
Accounts receivable	(162)	59
Prepaid expenses and other assets	(548)	(319)
Inventories	(144)	(5)
Accounts payable, accrued liabilities and other liabilities	2,248	1,594
Net cash used in operating activities	(27,395)	(14,734)
Cash flows from investing activities:		
Purchase of property and equipment	(184)	(490)
Net cash used in investing activities	(184)	(490)
Cash flows from financing activities:		
Principal repayment of DECD loan	(198)	(192)
Proceeds from DECD loan	-	2,000
Proceeds from issuance of common stock from exercise of stock options	718	1,637
Proceeds from PPP loan	-	1,006
Proceeds from exercise of warrants	-	5,060
Proceeds from private placement	-	11,025
Payment of issuance costs for private placement	-	(384)
Proceeds from public offering	48,235	-
Payment of offering costs for public offering	(377)	-
Net cash provided by financing activities	48,378	20,152
Net increase in cash, cash equivalents and restricted cash	20,799	4,928
Cash, cash equivalents and restricted cash, beginning of period	16,631	11,703
Cash, cash equivalents and restricted cash, end of period	$ 37,430	$ 16,631
Reconciliation to Consolidated Balance Sheet:		
Cash and cash equivalents	$ 37,180	$ 16,631
Restricted cash	250	-
Unrestricted and restricted cash and cash equivalents	$ 37,430	$ 16,631
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	77	37
Supplemental disclosure of noncash investing and financing activities:		
Net increase in right-of-use assets	-	354
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 together with its wholly-owned subsidiaries, 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 intended as an aid to further assess the likelihood of malignancy in women with an ovarian adnexal mass for which surgery is planned when the physician's independent clinical and radiological evaluation does not indicate malignancy; (2) OVERA, a second-generation biomarker reflex intended to maintain OVA1's high sensitivity while improving specificity; (3) OVA1plus, a reflex offering which uses OVA1 as the primary test and OVERA as a confirmation for OVA1 intermediate range results and 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 hereditary gynecologic cancer risk, with a core focus on hereditary female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers; and (5) Aspira Synergy, a decentralized testing platform and cloud service for decentralized global access of both protein biomarker and hereditary genetic testing. Through December 31, 2021, the Company's product and related services revenue has been limited to revenue generated by sales of OVA1, OVA1plus and Aspira GenetiX.

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 $471,728,000, as of December 31, 2021. The Company also expects to incur a net loss and negative cash flows from operations for 2022. In the event that the Company's existing cash on hand is not sufficient to fund operations, meet its capital requirements or satisfy the anticipated obligations as they become due, the Company expects to take further action to protect its liquidity position. Such actions may include, but are not limited to:

Raising capital through an equity offering either in the public markets or via a private placement offering (however, no assurance can be given that capital will be available on acceptable terms, or at all);
Reducing executive bonuses or replacing cash compensation with equity grants;
Reducing professional services and consulting fees and eliminating non-critical projects;
Reducing travel and entertainment expenses; and
Reducing, eliminating or deferring discretionary marketing programs.

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 through the beginning of the third quarter of 2020. Volumes started trending back to pre-COVID levels during the late third quarter of 2020. However, as various COVID-19 variants evolved, the Company experienced fluctuating testing volumes. 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, Key Opinion Leader presentations, and increased digital sales and marketing. Enrollment for clinical research studies has been slower than originally planned due to the impact of clinic closures and patients not seeking medical care in some states. The full impact of the COVID-19 pandemic continues to evolve as of the date these financial statements are first filed with the SEC. As a result, the Company is unable to estimate the extent of the impact of the COVID-19 pandemic on its operations or liquidity.

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. On the consolidated balance sheet, short-term debt of $400,000 was reclassified to long-term debt.

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.

Restricted Cash

Restricted cash consists of a security deposit for a financing arrangement.

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.

Inventory

The Company has inventory consisting primarily of kit inventory for specimen delivery as well as reagents used for specimen testing and miscellaneous inventory such as pipettes, gloves and other non-reagent items.

At each reporting period the Company reviews its inventories for obsolescence and writes down obsolete or otherwise unmarketable inventory to its estimated net realized value, which is primarily related to kit inventory when kits expire. Inventory is valued at cost.

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 Topic 606, *Revenue from Contracts with Customers* ("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 effect of any change made to an estimated input component and, therefore revenue recognized, would be recorded as a change in estimate at the time of the change.

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 years ended December 31, 2021 and 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, 2021 and 2020.

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.

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 to approximately $202,000 and $322,000 for the years ended December 31, 2021 and 2020, 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, restricted cash, 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 amount of restricted cash represents a long-term security deposit for a financial arrangement that is at cost. 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, 2021 and 2020 were as follows:

(in thousands)	December 31, 2021	2020
Machinery and equipment	$ 1,094	$ 1,094
Demonstration equipment	8	17
Computer equipment and software	1,252	1,194
Furniture and fixtures	174	154
Leasehold improvements	721	701
Gross property and equipment	3,249	3,160
Accumulated depreciation and amortization	(2,785)	(2,577)
Property and equipment, net	$ 464	$ 583

Depreciation expense for property and equipment was $302,000 and $265,000 for the years ended December 31, 2021 and 2020, respectively.

NOTE 5: ACCRUED LIABILITIES

The components of accrued liabilities as of December 31, 2021 and 2020 were as follows:

(in thousands)	December 31, 2021	2020
Payroll and benefits related expenses	$ 2,652	$ 1,874
Collaboration and research agreements expenses	382	616
Professional services	1,992	803
Other accrued liabilities	273	325
Total accrued liabilities	$ 5,299	$ 3,618

NOTE 6: COMMITMENTS, CONTINGENCIES AND DEBT

Long-term debt consisted of the following:

(in thousands)	December 31, 2021	2020
DECD loan, net of issuance costs	$ 2,919	$ 3,116
PPP Loan	-	1,006
Total debt	2,919	4,122
Less: Current portion, net of issuance costs	(201)	(645)
Total long-term debt, net of issuance costs	$ 2,718	$ 3,477

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 approximately $1,006,000. 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 was 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 used 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, was set to

mature on May 1, 2022. The Company applied for forgiveness of the PPP Loan in March 2021, and, effective May 27, 2021, the SBA confirmed the waiver of the Company's repayment of the PPP Loan. The Company recognized a gain on forgiveness of debt of approximately $1,006,000, which is included in other income in the condensed consolidated statements of operations and reduced long- and short-term indebtedness by the same amount. The Company remains subject to an audit of the PPP Loan. There is no assurance that the Company will not be required to repay all or a portion of the PPP Loan as a result of the audit.

Loan Agreement

On March 22, 2016, the Company entered into a loan agreement (as amended, the "DECD 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 DECD Loan Agreement. On December 3, 2020, the Company received a disbursement of the remaining $2,000,000 under the DECD Loan Agreement, as the Company had achieved the target employment milestone necessary to receive an additional $1,000,000 under the DECD Loan Agreement and the DECD determined to fund the remaining $1,000,000 under the DECD 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 DECD 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, 2021, the annual amounts of future minimum principal payments due under the Company's contractual obligation are shown in the table below. Unamortized debt issuance costs for the DECD loan were $15,000. Debt related to the insurance promissory note of $779,000, as described below, is not included in the following table due to the insurance promissory note being cancelable.

	Payments Due by Period						
(in thousands)	Total	2022	2023	2024	2025	2026	Thereafter
DECD Loan	$ 2,933	$ 204	$ 406	$ 452	$ 461	$ 341	$ 1,069
Total	$ 2,933	$ 204	$ 406	$ 452	$ 461	$ 341	$ 1,069

Insurance Notes

During 2021 and 2020, the Company entered into insurance promissory notes for the payment of insurance premiums at an interest rate of 3.74% and 3.88% respectively, with an aggregate principal amount outstanding of approximately $779,000 and $611,000 as of December 31, 2021 and 2020, respectively. The amount outstanding in 2021 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, 2022 and October 1, 2021, 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 research and development services is located in Trumbull, Connecticut. In October 2021, the Company renewed the Austin, Texas lease for one additional year. The Company's renewed lease expires on January 31, 2023, with no automatic renewal or renewal option. The Company's Texas lease has a term of 12 months, and the Company has elected the policy of not recording leases on the balance sheet when the leases have terms of 12 months or less. The Company recognized the lease payments in profit and loss on a straight-line basis over the term of the lease, and variable lease payments in the period in which the obligation for the payments was incurred.

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, 2021 and 2020 is shown in the table below (in thousands), of which $108,000 and $53,000 related to rent and variable costs, respectively, for the Texas lease.

		Twelve Months Ended December, 31	
Lease Cost	Classification	2021	2020
Operating rent expense			
	Cost of revenue	$ 59	$ 54
	Research and development	44	38
	Sales and marketing	33	26
	General and administrative	68	57
Variable rent expense			
	Cost of revenue	$ 32	$ 26
	Research and development	32	16
	Sales and marketing	37	45
	General and administrative	61	61

Based on the Company's leases as of December 31, 2021, the table below sets forth the approximate future lease payments related to operating leases with initial terms of one year or more (in thousands).

2022	$ 95
2023	106
2024	116
2025	124
2026	64
Total Operating Lease Payments	505
Less: Interest	(96)
Present Value of Lease Liabilities	$ 409

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

Weighted-average remaining lease term (in years)	4.5
Weighted-average discount rate	9.33%

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, 2021 and 2020 totaled $263,000 and $181,000, respectively, as recorded in cost of revenue in the condensed consolidated statements of operations.

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

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 $10,641,000, after deducting expenses related to the private placement of $384,000. The sale of common stock qualified for equity treatment under GAAP.

2021 Public Offering

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 Aspira common stock at a price to the public of $7.50 per share. The 2021 Underwriters purchased these 6,000,000 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 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 additional 900,000 shares of Aspira common stock, closed on February 8, 2021 and resulted in net proceeds to the Company of approximately $47,858,000, after deducting underwriting discounts and offering expenses of $377,000.

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, 2021 and 2020 was as follows:

(In thousands, except shares and per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
Year ended December 31, 2021:			
Net loss - basic	$ (31,662)	111,210,614	$ (0.28)
Dilutive effect of common stock shares issuable upon exercise of stock options	-	-	
Net loss - diluted	$ (31,662)	111,210,614	$ (0.28)
Year ended December 31, 2020:			
Net loss - basic	$ (17,905)	100,723,303	$ (0.18)
Dilutive effect of common stock shares issuable upon exercise of stock options	-	-	
Net loss - diluted	$ (17,905)	100,723,303	$ (0.18)

Due to net losses for the years ended December 31, 2021 and 2020, 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, 2021 and 2020 were as follows:

	Year Ended December 31,	
	2021	2020
Stock options	10,257,908	8,212,112
Potential common shares	10,257,908	8,212,112

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, 2021, a total of 4,366,311 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, 2021, there were 3,729,204 shares of Aspira common stock available for future grants under the 2019 Plan. As of December 31, 2021, there were 5,891,597 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, 2021 and 2020 was as follows:

	2010 Stock Option Plan	2019 Stock Option Plan	Total
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
Options canceled	95,626	1,321,646	1,417,272
Options granted	-	(4,020,634)	(4,020,634)
Restricted stock units granted	-	(76,742)	(76,742)
Shares forfeited	(95,626)	-	(95,626)
Shares available at December 31, 2021	-	3,729,204	3,729,204

The stock option activity under the 2010 Plan and the 2019 Plan for the years ended December 31, 2021 and 2020 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
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
Granted	4,020,634	6.22		
Exercised	(557,566)	1.29		
Canceled	(1,417,272)	4.34		
Options outstanding at December 31, 2021	10,257,908	$ 2.96	$ 3,797,181	7.44
Shares exercisable:				
December 31, 2021	4,773,394	$ 1.61	$ 2,182,917	5.91
Shares expected to vest:				
December 31, 2021	5,484,514	$ 4.14	$ 1,614,267	7.77

The range of exercise prices for options outstanding and exercisable at December 31, 2021 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	- $ 1.11		3,079,820	$ 0.78	7.49	1,723,473	$ 0.80
1.23	- 2.05		2,623,941	1.53	5.64	2,027,441	1.57
2.08	- 7.40		4,348,147	5.14	8.41	984,980	2.86
7.79	- 7.79		206,000	7.79	9.07	37,500	7.79
$ 0.47	- $ 7.79		10,257,908	$ 2.96	7.44	4,773,394	$ 1.61

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2021	$ 2,903	$ 4,325
Year ended December 31, 2020	$ 3,439	$ 3,254

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, 2021 and 2020 were as follows:

	Year Ended December 31, 2021	2020
Dividend yield	- %	- %
Volatility	89 %	84 %
Risk-free interest rate	0.63 %	0.71 %
Expected lives (years)	3.8	2.9
Weighted average grant date fair value	$ 3.94	$ 0.87

The allocation of employee and director stock-based compensation expense by functional area for the years ended December 31, 2021 and 2020 was as follows:

(in thousands)	Twelve Months Ended December 31, 2021	2020
Cost of revenue	$ 153	$ 96
Research and development	350	33
Sales and marketing	1,210	162
General and administrative	1,658	924
Total	$ 3,371	$ 1,215

As of December 31, 2021, total unrecognized compensation cost related to unvested stock option awards was approximately $12,110,000 and the related weighted average period over which it is expected to be recognized was 3.14 years. As of December 31, 2021, 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, 2021 and 2020, the Company did not make Company contributions to the 401(k) Plan.

NOTE 10: INCOME TAXES

There was no current income tax expense or benefit for the years ended December 31, 2021 or 2020 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, 2021 and 2020 were $31,662,000 and $17,905,000, 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, 2021 and 2020. Therefore there was no deferred income tax expense or benefit for the years ended December 31, 2021 or 2020.

The components of net deferred tax assets (liabilities) at December 31, 2021 and 2020 were as follows:

	Year Ended December 31,	
(in thousands)	2021	2020
Deferred tax assets:		
Net operating losses	$ 38,268	$ 32,740
Amortization - R&D intangibles	2,404	1,873
Depreciation and amortization	633	622
Other	587	-
Total deferred tax assets	41,892	35,235
Valuation allowance	(41,892)	(35,195)
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, 2021 and 2020 was as follows:

	Year Ended December 31,	
	2021	2020
Tax at federal statutory rate	21 %	21 %
State tax, net of federal benefit	(2)	1
Valuation allowance	(21)	(19)
Net operating loss and tax credit carryforwards	-	(2)
Permanent items	1	(1)
Other	1	-
Effective income tax rate	- %	- %

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 net operating losses ("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 of $91,000,000, which are not limited from offsetting future taxable income under Section 382, will expire in varying amounts from 2022 through 2037, if not utilized and can offset 100% of future taxable income for regular tax purposes. The Company's federal NOLs of $82,000,000 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 2022 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 to offset future taxable income is restricted due to ownership change limitations that have occurred in the past, as required by Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state provisions. Net operating losses which are limited from offsetting any future taxable income under Section 382 are not included in the gross deferred tax assets presented above.

The valuation allowance was approximately $41,892,000 and $35,195,000 at December 31, 2021 and 2020, respectively. The increase of approximately $6,700,000 between 2020 and 2021 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, 2021, the Company's federal returns for the years ended 2018 through the current period and most state returns for the years ended 2017 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 2018 and 2017, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2020 reflect research and development carryforwards of $5,112,000 and $5,396,000, respectively. For the year ended December 31, 2021, the Company anticipates claiming additional research and development credits of $260,000 on its federal tax return and $248,000 on its California tax return.

As of December 31, 2021, the Company's gross unrecognized tax benefits are approximately $10,581,000 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, 2019	$ 5,293	$ 5,351	$ 10,644
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
Return to provision true up	(9)	-	(9)
Increase in tax position during 2021	260	248	508
Decrease due to expirations during 2021	(435)	-	(435)
Balance at December 31, 2021	$ 4,937	$ 5,644	$ 10,581

The increase for the year ended December 31, 2021 relates to positions taken in the current year, which are substantially offset by the expiration of a portion of the carryforward. The decrease for the year ended December 31, 2020 is related primarily to the expiration of a portion of the carryforward. If the $10,581,000 of unrecognized income tax benefit is recognized, approximately $10,581,000 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, 2021 and 2020. Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

NOTE 11: RELATED PARTY TRANSACTIONS

In March 2021, the Company entered into a consulting agreement, as amended, with David Schreiber, pursuant to which Mr. Schreiber performed certain consulting services for the Company after his service on the Company’s board of directors had concluded.

NOTE 12: SUBSEQUENT EVENTS

In connection with our Strategic Research Collaboration Agreement for the development and commercialization of a Micro RNA high risk ovarian cancer early-detection test with Harvard Dana-Farber Cancer Institute, Brigham and Women’s Hospital and Medical University of Lodz, during March 2022, the Company exercised the option for an exclusive world-wide license of this cutting-edge miRNA technology and plans to continue development of a novel combined assay utilizing a new platform with the Company’s collaborators.

During the first quarter of 2022, the Company executed a reorganization resulting in the separation of a number of employees. The organizational changes will result in the recording of one-time severance, separation, and settlement payments as well as legal costs in the first quarter of approximately $1,258,000 including estimated future payouts, partially offset by insurance reimbursement of $523,000.

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, 2022

/s/ Nicole Sandford
Nicole Sandford
President and Chief Executive Officer (Principal Executive Officer)

Date: March 31, 2022

/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/ Nicole Sandford Nicole Sandford	President and Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2022
/s/ Robert Beechey Robert Beechey	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2022
/s/ Valerie B. Palmieri Valerie B. Palmieri	Executive Chair of the Board of Directors and Director	March 31, 2022
/s/ James T. LaFrance James T. LaFrance	Director	March 31, 2022
/s/ Celeste Fralick Celeste Fralick	Director	March 31, 2022
/s/ Veronica G. H. Jordan Veronica G. H. Jordan	Director	March 31, 2022