

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, 2022 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**

(State or Other Jurisdiction of Incorporation or Organization)

**12117 Bee Caves Road, Building III, Suite 100**

**Austin, Texas**

(Address of Principal Executive Offices)

**33-0595156**

(I.R.S. Employer Identification No.)

**78738**

(Zip Code)

**Registrant's telephone number, including area code: (512) 519-0400**

**Securities registered pursuant to Section 12(b) of the Act:**

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>Common Stock, par value \$0.001 per share</b>	<b>AWH</b>	<b>The Nasdaq Capital Market</b>

**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 **£**

Non-accelerated filer **T**

Accelerated filer **£**

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**

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 \$50,183,661 and is based upon the last sales price as quoted on The Nasdaq Capital Market as of June 30, 2022.

As of March 20, 2023, the registrant had 124,943,144 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 2023 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, 2022.

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# ASPIRA WOMEN'S HEALTH INC.

## FORM 10-K

For the Fiscal Year Ended December 31, 2022

### Table of Contents

	<b>Page No.</b>
<b>PART I</b>	<b>3</b>
ITEM 1. Business	3
ITEM 1A. Risk Factors	19
ITEM 1B. Unresolved Staff Comments	33
ITEM 2. Properties	33
ITEM 3. Legal Proceedings	33
ITEM 4. Mine Safety Disclosures	33
<b>PART II</b>	<b>34</b>
ITEM 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	34
ITEM 6. [Reserved]	35
ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	36
ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk	44
ITEM 8. Consolidated Financial Statements and Supplementary Data	44
ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	44
ITEM 9A. Controls and Procedures	44
ITEM 9B. Other Information	46
ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	46
<b>PART III</b>	<b>47</b>
ITEM 10. Directors, Executive Officers and Corporate Governance	47
ITEM 11. Executive Compensation	47
ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	47
ITEM 13. Certain Relationships and Related Transactions, and Director Independence	47
ITEM 14. Principal Accountant Fees and Services	47
<b>PART IV</b>	<b>48</b>
ITEM 15. Exhibits and Financial Statement Schedules	48
ITEM 16. Form 10-K Summary	51
<b>SIGNATURES</b>	<b>F-26</b>

The following are registered and unregistered trademarks and service marks of Aspira Women's Health Inc.: VERMILLION®, ASPIRA WOMEN'S HEALTH®, OVA1®, OVERA®, ASPIRA LABS®, OVACALC®, OVASUITE<sup>SM</sup>, ASPIRA GENETIX<sup>SM</sup>, OVA1PLUS®, OVAWATCH<sup>SM</sup>, ENDOCHECK™, OVAINHERIT™, ASPIRA SYNERGY<sup>SM</sup>, OVA360<sup>SM</sup>, ASPIRA IVD®, OVASUITE<sup>SM</sup>, and YOUR HEALTH, OUR PASSION®.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”), about us and our industry that involve substantial risks and uncertainties.

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, price, cost of revenue, operating expenses, research and development expenses, gross profit margin, cash flow, results of operations and financial condition;  
whether we are able to maintain the listing of our common stock on the Nasdaq Capital Market;  
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;  
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 and Aspira Synergy on a global level, and to launch and commercialize our new products, OvaWatch and EndoCheck;  
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 ovarian cancer that is difficult to detect through a diagnostic test;  
plans to establish payer coverage and secure contracts for current and new products, including OvaWatch and EndoCheck separately and expand current coverage and secure contracts for Ova1, Overa and Ova1Plus;  
expectations regarding coverage under Novitas, the Company’s Medicare Administrative Carrier 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, Inc. (“Aspira Labs”), including plans to expand or consolidate Aspira Labs’ testing capabilities;  
expectations regarding continuing future services provided by Quest Diagnostics Incorporated;  
expectations regarding continuing future services provided by BioReference Health, LLC;  
plans to develop informatics products and develop and perform laboratory developed tests (“LDTs”);  
Food and Drug Administration (“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 and provide and expand access to our risk assessment tests;  
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, including regulations applicable to the operation of our clinical labs, 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 and capital requirements;

anticipated future losses and our ability to continue as a going concern;  
expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations;  
expectation regarding attribution and recruitment of top talent;  
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 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, as well as procure serum samples from other potential partnerships or studies;  
potential plans to pursue clearance designation with the FDA with respect to EndoCheck and OvaWatch;  
expected target launch timing for OvaWatch Phase II 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;  
expectations regarding the impacts resulting from or attributable to the COVID-19 pandemic and actions taken to contain it;  
plans regarding discontinuing the Aspira GenetiX product and related genetics testing offerings; and  
expectations regarding the results of our academic research agreements.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K.

Other sections of this Annual Report on Form 10-K may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those contained in, or implied by, any forward-looking statements.

Forward-looking statements are subject to significant risks and uncertainties, including those discussed in Part I Item 1A, "Risk Factors," that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including our ability to continue as a going concern; our ability to comply with Nasdaq's continued listing requirements; impacts resulting from potential changes to coverage of Ova1 through our Medicare Administrative Carrier for Ova1; 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 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.

## PART I

### ITEM 1. BUSINESS

#### Company Overview

**Corporate Vision:** Our core mission is to transform women's gynecologic health through the development of technology-enabled diagnostic tools, 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 plan is to broaden our focus to the differential diagnoses of other gynecologic diseases that typically cannot be assessed through traditional non-invasive clinical procedures. We expect to continue commercializing our existing and new technology and to distribute our tests through our decentralized technology transfer service platform, Aspira Synergy. We also intend to continue to raise public awareness regarding the diagnostic superiority of Ova1 as compared to cancer antigen 125 ("CA125") on its own for all women, but especially for racially diverse women with adnexal masses, as well as the superior performance of machine learning algorithms in detecting ovarian cancer in different racial and ethnic populations. We plan to continue to expand access to our tests among Medicaid patients as part of our corporate mission to make the best care available to all women, and we plan to advocate for legislation and the adoption of our technology in professional society guidelines to provide broad access to our products and services.

Throughout 2022, we have focused on three key initiatives: growth, innovation, and operational excellence:

**Growth.** In 2022, we have continued to grow Ova1Plus product volume and revenue through our commercial team. Throughout the year, we aimed not only to increase the number of physicians ordering for the first time but also to increase repeat orders from existing physician customers. Positive trends in the tenure of our sales professionals have led to year-over-year volume growth. In addition, in October 2022, we launched a co-marketing and distribution collaboration with BioReference Health, LLC (formerly known as BioReference Laboratories, Inc.), a subsidiary of OPKO Health, Inc. ("BRL"), as a new channel for volume growth. Also in the fourth quarter, we announced that the American Medical Association assigned a new Proprietary Laboratory Assay code for OvaWatch, which will enable payers to identify OvaWatch specifically in the claims adjudication process beginning in April 2023. In addition, the Federal Omnibus bill passed by Congress in December 2022 mandates coverage for multi-marker testing for ovarian cancer, such as Ova1Plus and OvaWatch via a National Coverage Determination within 180 days of the bill's effective date. The Company secured credentialing or pricing for Medicaid and Managed Medicaid population in many new states in 2022.

**Innovation.** Innovation is fundamental to the long-term success of any diagnostics company. For Aspira, it starts with the expansion of our ovarian cancer portfolio, which is now branded as OvaSuite. Our first Lab Developed Test ("LDT"), OvaWatch, is a non-invasive ovarian cancer risk assessment for women with adnexal masses to be used by physicians as part of initial clinical assessment. This assay will significantly expand our patient population beyond the population that existed for Ova1Plus. OvaWatch was designed to be launched in two phases. The first phase, a one-time use test for initial clinical assessment, was launched in the fourth quarter of 2022. We intend to launch the second phase, which will be used for serial mass monitoring, in 2023. In 2022, the Company published two OvaWatch manuscripts in peer-reviewed journals: "Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer," published online in the Journal of Clinical Oncology Clinical Cancer Informatics and "Validation of Deep Neural Network-based Algorithm Supporting Clinical Management of Adnexal Mass," published in the high impact journal, Frontiers in Medicine.

We plan to accelerate the development of our endometriosis product portfolio by supplementing our internal development and validation program with our partnership with Harvard's Dana-Farber Cancer Institute ("DFCI"), Brigham & Women's Hospital ("BWH"), and Medical University of Lodz through a sponsored research agreement that we entered into in the third quarter of 2022. We are committed to launching a first-generation non-invasive endometriosis diagnostic tool in the second half of 2023.

We believe the Company's competitive positioning is superior to other diagnostic companies as our processes to develop and validate new LDTs are performed in a CLIA laboratory environment. This allows for the acceleration of assay commercialization without sacrificing patient care.

**Operational Excellence.** We achieved our cash utilization goals for 2022 by focusing on spending that accelerates innovation and growth. We plan to maintain the right employee talent and scale to achieve our goals and drive efficiencies in 2023.

**Mission Statement.** Our core mission is to transform women's gynecologic health through the development of technology-enabled diagnostic tools, 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.

#### **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 cancer and other complex diseases are 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 tools 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 to gain pre-market authorization from the FDA. In the case of Ova1, the FDA granted a request for *de novo* 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.

**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 test 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%; and (4) OvaWatch, a lab developed blood test intended to assist in the initial clinical assessment of malignancy risk in all women thought to have an indeterminate or benign adnexal mass. Collectively, these tests are referred to and marketed as OvaSuite. Our products are distributed through our own national sales force, through our proprietary decentralized testing platform and cloud service marketed as Aspira Synergy, and through a marketing and distribution agreement with BioReference Health, LLC (formerly known as BioReference Laboratories, Inc.), a subsidiary of OPKO Health, Inc.

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, Overa and OvaWatch, our first LDT, each use the Roche Cobas 4000, 6000 and 8000 platforms for analysis of proteins. Revenue from these sources (in addition to revenue from Aspira GenetiX, which was discontinued in September 2022) is included in the results of operations in total revenue for the year ended December 31, 2022.

In 2021, we began entering into decentralized arrangements with large healthcare networks and physician practices for our Aspira Synergy platform, our decentralized testing platform and cloud service for decentralized global access of protein biomarker testing. Ova1, Overa, and Ova1Plus continue to be available through the Aspira Synergy platform. We have entered into four technology transfer agreements since the launch of Aspira Synergy. Two of the agreements are with independent regional laboratories and are in the process of being launched and piloted. One of the agreements is with one of the nation's largest and leading independent women's healthcare groups which has already launched and is contributing to our Ova1Plus volume. The last of the four agreements with Axia Women's Health, which had been intended to deliver genetics carrier screening, was cancelled by the customer in the third quarter of 2022. This cancellation, along with the general deterioration of commercial opportunities in the genetics carrier screening market, has led us to cease providing Aspira GenetiX, including

genetics carrier screening, on our Aspira Synergy platform, effective as of September 30, 2022. This did not have a material impact on our revenues in 2022, nor do we expect it to have a material impact in any future periods.

OvaWatch has been developed and is validated for use in Aspira's CLIA-certified lab as a non-invasive blood-based risk assessment test for use in conjunction with clinical assessment and imaging to determine ovarian cancer risk for patients with an adnexal mass whose adnexal mass has been determined by an initial clinical assessment as indeterminate or benign. The commercialization plan for OvaWatch will occur in two phases. Phase I, which was launched during the fourth quarter of 2022, is a single use, point-in-time risk assessment test and Phase II will allow for serial monitoring. The launch of the serial monitoring test is targeted for the second half of 2023 following the expected publication of data from the ongoing prospective serial monitoring clinical study. We believe OvaWatch has the potential to significantly expand the addressable market compared to Ova1Plus.

Outside of the United States, we have sponsored studies in both the Philippines and Israel, which are intended to validate Overa and Ova1 in specific populations. In June 2022, a manuscript arising from clinical research efforts in the Philippines, which we sponsored, was accepted for publication in the *International Journal of Environmental Research and Public Health*. The Philippines study is the first application of Aspira Synergy for Overa specimen testing. The first paper from the Philippines study was published in the third quarter of 2022.

We own and operate 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 performs our Ova1, Overa, Ova1Plus, and OvaWatch testing as well as additional tumour and hormone tests, and we plan to expand the testing to other gynecologic conditions with high unmet need. Aspira Labs holds a 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. Aspira labs also hold a current ISO 13485 certification which is the most accepted standard worldwide for medical device.

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 billed by the Company being performed exclusively at Aspira Labs in Texas, the local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. Aspira Labs also bills third-party commercial and other government payers as well as client bill accounts and patients for Ova1.

In November 2016, the American College of Obstetricians and Gynecologists ("ACOG") issued Practice Bulletin Number 174 which included Ova1, defined as the "Multivariate Index Assay", outlining ACOG's clinical management guidelines for adnexal mass management. Practice Bulletin Number 174 recommends that obstetricians and gynecologists evaluating women with adnexal masses who do not meet Level A criteria of a low-risk transvaginal ultrasound should proceed with Level B clinical guidelines. Level B guidelines state that the physician may use risk assessment tools such as existing CA-125 technology or Ova1 ("Multivariate Index Assay") as listed in the bulletin. Based on this, Ova1 achieved parity with CA-125 as a Level B clinical recommendation for the management of adnexal masses.

Practice Bulletins summarize current information on techniques and clinical management issues for the practice of obstetrics and gynecology. Practice Bulletins are evidence-based documents, and recommendations are based on the evidence. This is also the only clinical management tool used for adnexal masses. Although there are Practice Bulletins, guidelines do not exist for adnexal masses. ACOG guidelines do exist, however, for ovarian cancer management.

## Product Pipeline

We are well positioned to introduce new gynecologic diagnostic products and we plan to expand our product offerings to additional women's gynecologic health diseases 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. Future product expansions will be accelerated by the development of lab developed testing in a CLIA environment, or relationships with strategic research and development partners, and access to specimens in our biobank.

**About OvaWatch serial testing:** OvaWatch is a non-invasive blood-based risk assessment test to determine ovarian cancer risk for patients with an adnexal mass whose adnexal mass has been determined by an initial clinical assessment as indeterminate or benign. OvaWatch is designed to support a physician's planned clinical management through additional clinical



data at the time of initial assessment, and by potentially monitoring - in conjunction with ultrasounds and other clinical assessments - to safely decrease or delay unnecessary surgery.

The test was developed through a rigorous scientific and clinical-based process and validated in a CLIA environment utilizing large retrospective cohorts of over 3,000 patients and multi-site prospective clinical studies. OvaWatch technology was validated for this application in two separate prospective cohorts of women. The first cohort was patients with an identified pelvic mass and symptoms. The second cohort was women whose pelvic mass is found incidentally and are asymptomatic, and that are also not scheduled for surgery.

OvaWatch was designed for launch in two stages. Phase I, which was launched during the fourth quarter of 2022 is a single use point in time test, and Phase II will allow for serial monitoring. The launch of the serial monitoring test is targeted for 2023 upon obtaining sufficient data from the ongoing prospective serial monitoring clinical study. Phase I of the OvaWatch test has a 99% negative predictive value, which will allow physicians to initially assess and serially monitor women with a mass to safely delay or reduce premature or unnecessary surgery.

In 2022, we published two OvaWatch manuscripts: "Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer," published online in the Journal of Clinical Oncology Clinical Cancer Informatics; and "Validation of Deep Neural Network-based Algorithm Supporting Clinical Management of Adnexal Mass," published in the high impact, peer-reviewed journal, Frontiers in Medicine.

**About EndoCheck:** EndoCheck, an in-development non-invasive blood test to be used in conjunction with other non-surgical modalities, is designed as an aid in the identification of endometriosis to guide clinical care for patients with suspected endometriosis earlier in their prognosis journey. 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 comparable sensitivity and specificity when compared to invasive methods such as surgical biopsy and/or visualization. We expect that our research collaboration agreement with DFCI, BWH, and Medical University of Lodz will accelerate commercialization of our endometriosis product portfolio. Our goal is to launch an EndoCheck LDT in the second half of 2023.

We ultimately plan to commercialize OvaSuite and EndoCheck on a global scale and hold CE marks for Ova1 and Overa. In June 2022, in connection with our global expansion plans, a manuscript arising from clinical research efforts in the Philippines, which we sponsored, was accepted for publication in the *International Journal of Environmental Research and Public Health*. The study was designed to validate the effectiveness of a multivariate index assay ("MIA2G") Overa in the assessment of ovarian cancer in Filipino women. The resulting data indicated that MIA2G (Overa) exhibited better overall performance in detecting ovarian cancer, regardless of menopausal status, compared to CA-125 test measures. Notably, MIA2G (Overa) was shown to be more sensitive in detecting early-stage disease for this population than CA-125. The study also showed that MIA2G (Overa) had the best overall performance of all individual classifiers, including in some of the most difficult to detect cancers cohorts such as premenopausal women, and early-stage disease.

## Studies and Publications

On June 16, 2022, we announced the online publication of a paper entitled "*Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer*," in the June issue of JCO Clinical Cancer Informatics. The paper validates the OvaWatch algorithm in the detection of ovarian cancer and demonstrates the potential of OvaWatch in assessing the risk of ovarian malignancy in patients with pelvic masses, which are indeterminate or benign.

On September 12, 2022, we announced publication of a study, "*Clinical Performance of a Multivariate Index Assay in Detecting Early-Stage Ovarian Cancer in Filipino Women*," in the peer-reviewed International Journal of Environmental Research and Public Health. The study concluded that incorporating MIA2G (OVERA) rather than CA-125 into clinical assessment would increase the detection of early-stage ovarian cancers, regardless of menopausal status.

On January 6, 2023, we announced a manuscript, "Validation of Deep Neural Network-based Algorithm Supporting Clinical Management of Adnexal Mass," had been published in the prestigious and high impact, peer-reviewed journal, Frontiers in Medicine. The paper presents findings from the multi-site clinical study of the company's new assay, OvaWatch, describing real-world evidence supporting the use of OvaWatch for the clinical management of adnexal masses.

The Company has a number of ongoing clinical studies to support the development of our product pipeline. In addition to our ongoing clinical study for the validation of serial monitoring using the OvaWatch mass monitoring test, in 2022 we launched a study to support the validation of our to-be-launched EndoCheck test. The goal of this observational study is to determine the clinical validity of a machine learning based algorithm that utilizes protein biomarker to detect Endometriosis - "EndoCheck" - as an additional diagnostic assessment tool for endometriosis. We also support ongoing ex-U.S. studies in the Philippines and Israel.

**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 2022, Fortune Business Insight, a market research and business consulting partnership, published a study which forecasts the global *in vitro diagnostic* (“IVD”) market to reach \$107.42 billion by 2029, growing at a compound annual growth rate of 6% from 2022 to 2029. 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. In 2022, The American Cancer Society (“ACS”) estimated that nearly 20,000 new ovarian cancer cases were 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. The 5-year survival rate falls to as low as 31% for ovarian cancer patients diagnosed in the late-stages of the disease.

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. 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. 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%.<sup>[1]</sup> 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%.<sup>[2]</sup> 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. When managing an adnexal mass, physicians will either take a surgical management approach or a clinical management approach. Patients that do require surgical management could potentially benefit from the use of Ova1Plus. Patients not referred for surgical intervention may benefit from the use of OvaWatch to confirm the low risk of malignancy of a mass that was determined to be indeterminate or benign by initial clinical assessment.

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 31% of early-stage ovarian cancer cases.<sup>[3]</sup> 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.”<sup>[4]</sup>

The ovarian cancer information page on American Cancer Society’s website 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.<sup>[5]</sup>

Aspira is committed to developing diagnostic tools for women of all ages, races and ethnicities. 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.<sup>[6][7]</sup> In 2022, another study was released indicating superior clinical performance of Ova1 over CA125 in Filipino women.<sup>[8]</sup>

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 Longoria, T. C., Ueland, F. R., Zhang, Z., Chan, D. W., Smith, A., Fung, E. T., ... & Bristow, R. E. (2014). Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer. *American journal of obstetrics and gynecology*, 210(1), 78-e1.  
Dearing, A. C., Aletti, G. D., McGree, M. E., Weaver, A. L., Sommerfield, M. K., & Cliby, W. A. (2007). How relevant are ACOG and SGO guidelines for referral of adnexal mass?. *Obstetrics & Gynecology*, 110(4), 841-848.

4 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.

5 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.

6 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.

7 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.

8 Velayo CL, Reforma KN, Sicam RVG, Diwa MH, Sy ARD, Tantengco OAG. Clinical Performance of a Multivariate Index Assay in Detecting Early-Stage Ovarian Cancer in Filipino Women. June 2022.

## Commercialization and Distribution

The Company markets and distributes its products through 1) a national sales team, 2) the Aspira Synergy cloud-based technology transfer platform, and 3) various commercial partnerships. In October 2022, we launched a co-marketing and distribution collaboration with BioReference Health, LLC (formerly known as BioReference Laboratories, Inc.), a subsidiary of OPKO Health, Inc. (“BRL”), as a new channel for volume growth. Under terms of the agreement, the Aspira and BioReference sales teams will collaborate to sell Ova1Plus to gynecologists and other women’s healthcare providers nationwide.

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, our customer specimens are sent directly to us, and we bill either through payer contracts or client bill arrangements. We also offer access to our Ova1 and Overa assays 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, Harvard’s Dana-Farber Cancer Institute, Brigham & Women’s Hospital and Medical University of Lodz. 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. In 2022, another study demonstrated the superiority of Overa over CA125 in Filipino women.

In 2022 and early 2023, two OvaWatch peer-reviewed validations were published. The first, “*Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer*,” validates the OvaWatch algorithm in the detection of ovarian cancer and demonstrates the potential of OvaWatch in accurately assessing the risk of ovarian malignancy in patients with pelvic masses. Ovarian cancer is the deadliest gynecologic cancer, with most cases being diagnosed at late stage. Early detection of ovarian cancer is key to helping to reduce mortality; however, other current non-invasive risk assessment measures on the market vary in their usefulness. The other paper, “*Validation of Deep Neural Network-based Algorithm Supporting Clinical Management of Adnexal Mass*,” presents findings from the multi-site clinical study of the Company’s new assay, OvaWatch, describing real-world evidence supporting the use of OvaWatch for the clinical management of adnexal masses.

## **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 21,423 OvaSuite tests, inclusive of OvaWatch, were performed in 2022 compared to 17,377 in 2021, which included only Ova1Plus tests. In 2022, we continued to increase sales through Market Development Managers. 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.

Aspira Women’s Health successfully launched a comarketing arrangement for Ova1Plus with BioReference Laboratories on October 5, 2022. Under terms of the agreement, the Aspira and BioReference sales teams will collaborate to sell Ova1Plus to gynecologists and other women’s healthcare providers nationwide.

We believe OvaWatch will have a significant impact on the ordering behavior of physicians with respect to our ovarian cancer blood tests. Unlike Ova1Plus, which is indicated for use only for women with adnexal masses that have been identified for surgery, OvaWatch was developed for use with women with adnexal masses that have been identified as either benign or indeterminate through initial clinical assessment. It is estimated that physicians see three or more times as many women with benign or indeterminate masses compared to women with masses that are planned for surgery. In addition, we believe that the OvaWatch serial monitoring test that is planned for commercial launch in the second half of 2023 will further expand the patient population and the ordering frequency of our ovarian cancer blood tests.

## **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, 2022, Aspira’s product and related services revenue has primarily been limited to revenue generated by sales of Ova1Plus and Aspira GenetiX (discontinued in September 2022) and OvaWatch (launched in December 2022) generating minimal revenue throughout 2021 and 2022.

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 announced in 2022 that it would delay the period during which rates would be evaluated for another year. Therefore, the company will not be responsible for providing reimbursement rates until 2024.

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. The United States Congress included a provision in the 2023 Omnibus Spending Bill that called for the national Medicare coverage of multi-marker blood tests for ovarian cancer within 180 days. If this provision results in a National Coverage Determination, we believe this could further expand coverage and drive adoption.

In 2022, we added 7 new credentialed Medicaid states, which brought the total number of covered lives to approximately 215 million as of December 31, 2022, representing approximately 60% of the lives in the U.S.

We have a comprehensive reimbursement plan for OvaWatch, including a local coverage determination reconsideration request to Novitas to replicate the coverage policy for Ova1. In addition, we have secured a PLA code from the AMA that distinguishes OvaWatch from all other available testing. In February 2023, the Company signed a contract with a major global commercial payer which provides for patient coverage for OvaWatch beginning in April 2023.

## 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.

A number of diagnostic and academic organizations have announced plans or published studies related to the development of a non-invasive diagnostic tool for the identification of endometriosis. If successful, the product may be competitive with our to-be-launched EndoCheck LDT. Competitors include, but are not limited to, Dot.Labs, Ziwig, and Endodiag. We believe our experience developing multi-biomarker assays, particularly those focused on gynecologic diseases and pelvic masses, as well as our experienced women's health field sales team and our focus on developing a clinical assay in our CLIA laboratory environment, is a significant competitive advantage. We also believe that our biobank is another significant advantage.

## **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, 12 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 FDA cleared products Ova1 and Overa as well as a lab-developed test, OvaWatch. The component assays 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. Only reagent lots determined by us as having met these specifications are permitted for use in our testing. Our principal supplier is Roche Diagnostics Corporation. Our standard practice is to have at least four months of reagents on hand at any time.

## **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 (“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. 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”) or other applications, 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 that are device manufacturers. 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 serious, a warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA may 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***

Unless subject to an exemption, medical devices require prior FDA authorization before they may be commercially marketed. Devices can be legally sold within the U.S. only if the FDA has: (i) approved application for pre-market approval application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a 510(k) premarket notification submission, (“510(k)”), generally applicable to Class I and II devices; or (iii) reclassified the device pursuant to the *de novo* classification process, available for novel low or moderate risk devices. PMA applications, 510(k) premarket notifications, and *de novo* classification 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. A 510(k) may need to be supported by clinical data.

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 FDA's review clock. The applicant has 180 days to respond. Therefore, the total review time could be up to 270 days, although it can take longer.

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 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 generally requires clinical data. As part of the *de novo* process FDA will establish special controls to help ensure the safety and effectiveness of the device.

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 FDA's review clock. The applicant has 180 days to respond. Therefore, the total review time could be as long as 330 days, although it can take longer.

### ***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 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 FDA's 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, although it could take longer.

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, post-approval studies and 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 device studies, 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 study does not require FDA approval of an IDE, although it does need to comply with some elements of the IDE regulations. 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. Clinical trials of IVDs that meet certain regulatory criteria are exempt from the IDE regulations.

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 commercialization. Clinical trials, for both significant and nonsignificant risk device studies, as well as exempt IVD studies, 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. Informed consent of patients participating in the study generally must be obtained before they may participate in the study.

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 to devices subject to FDA's IDE regulations. 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, complaint 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 if that violation may present a risk to health). Failure to properly identify reportable events or to file timely reports, as well as failure to comply with other regulatory requirements, can subject a manufacturer to warning letters, recalls, or other sanctions and penalties.

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.

Marketing and promotional activities for devices, and advertising of some restricted medical devices, are also subject to FDA oversight and must comply with the statutory standards of the FDC Act, and the FDA's regulatory requirements. 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 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 that are consistent with those 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 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, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. 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 impose post-market conditions of approval, such as 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 studies of our IVD products, such as OvaWatch (formerly known as OvaNex), 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.

### ***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 when FDA deems it appropriate to address significant public health concerns.

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 risk-based 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. FDA has indicated that in the absence of congressional action it may try adopting regulations that would cover LDTs.

The FDA has become increasingly active in addressing the regulation of software used to support clinical decision making. In 2016, the 21st Century Cures Act, (the “Cures Act”), among other things, amended the medical device definition in the FDC Act to exclude certain software from FDA regulation, including clinical decision support, (“CDS software”), that meets certain criteria. CDS software is exempt from the medical device definition if it: (a) displays, analyzes or prints medical information about a patient or other medical information; (b) is intended for the purpose of supporting or providing recommendations about a patient’s care to a health care professional, (“HCP”), user; and (c) provides sufficient information about

the basis for the recommendations to the HCP user, so that the HCP user does not rely primarily on any of the recommendations to make a clinical decision about an individual patient; unless (d) the software function acquires, processes, or analyzes a medical image, a signal from an in vitro diagnostic device, or a pattern or signal from a signal acquisition system.

On September 28, 2022, the FDA issued a final guidance document interpreting the Cures Act as it pertains to CDS software. Among other views expressed, the final guidance stated that software functions that assess or interpret the clinical implications or clinical relevance of a signal or pattern, such as those that process or analyze an electrochemical or photometric response generated by an assay and instrument to generate a clinical test result, are not exempt from medical device regulation. The final guidance also stated that software functions that generate risk probabilities or risk scores are not exempt because they necessarily provide a specific diagnostic, preventive, or treatment output.

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, 2022, we had 85 full-time 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](http://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](http://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](http://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](http://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, "Consolidated Financial Statements and Supplementary Data." If any of the following risks materializes, our business, financial condition, results of operations and growth prospects could be materially adversely affected, and the value of an investment in our common stock may decline significantly. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition, results of operations and growth prospects.*

### RISKS RELATED TO OUR BUSINESS AND INDUSTRY

***If we fail to maintain compliance with the Nasdaq minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.***

The continued listing standards of the Nasdaq Capital Market require, among other things, that the minimum price of a listed company's stock be at or above \$1.00, or the Bid Price Requirement. If the minimum bid price is below \$1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq Capital Market's listing rules and, if it does not regain compliance within the 180-day grace period, will be subject to delisting. On June 1, 2022, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that we were not in compliance with the Bid Price Requirement. We did not regain compliance on or prior to November 28, 2022, and on November 29, 2022, we received a written notice from the Listing Qualifications Department of The Nasdaq Stock Market that we had been granted an additional 180 calendar days, or until May 29, 2023 (as the first trading day following such period), to regain compliance with the Bid Price Requirement.

In order to regain compliance, the bid price of our common stock must close at a price of at least \$1.00 per share for a minimum of 10 consecutive trading days within the 180 day grace period. If we fail to regain compliance, our common stock will be subject to delisting. Delisting from the Nasdaq Capital Market could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

***Unless our common stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.***

If we are unable to maintain the listing of our common stock on the Nasdaq Capital Market or another national securities exchange, our common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than \$5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than \$5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. This means that if we are unable maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected. If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

***If we are unable to increase the volume of OvaSuite 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 2023. 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 tests performed in 2021 and in 2022 was 17,377 and 21,423, respectively. If we are unable to increase the volume of OvaSuite sales, our business, results of operations and financial condition will be adversely affected.

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

We have incurred significant losses and negative cash flows from operations since inception and have an accumulated deficit of \$498.9 million as of the end of the period covered by this report. We also expect to incur a net loss and negative cash flows from operations in 2023 and have limited cash balances. Given these conditions, there is substantial doubt about our ability to continue as a going concern. The substantial doubt about our ability to continue as a going concern may adversely affect our stock price and our ability to raise capital. Our independent registered public accounting firm has also included in its report an explanatory paragraph regarding this uncertainty.

We believe that successful achievement of our business objectives will require additional financing. We expect to raise capital through a variety of sources that may include public or private equity offerings, debt financing, collaborations, licensing arrangements, grants and government funding and strategic alliances. However, in part due to our low stock price, additional financing may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may not be able to continue sales and marketing, research and development, distribution or other operations on the scope or scale of current activity and that could have a material adverse effect on our business, results of operations and financial condition. The accompanying financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern.

***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 current revenues are, and 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, OvaWatch 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, OvaWatch 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.

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

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

***Failure to continue coverage of Ova1 through Novitas, the Company's Medicare Administrative Carrier for Ova1 could materially and adversely affect our business, financial condition and results of operation.***

Since 2013, Ova1 has been listed as a covered service in the Biomarkers for Oncology Local Coverage Determination ("LCD") issued by Novitas, a Medicare Administrative Carrier. Earlier this year, Novitas issued a statement for public comment regarding the potential creation of a new LCD that could impact services previously included in the Biomarkers for Oncology LCD beginning in the second quarter of 2023. In related public statements, Novitas indicated a potential retirement of the Biomarkers for Oncology LCD. While we do not believe Novitas intends to eliminate Ova1 coverage, it has not provided additional information to allow us to assess the likelihood or potential impact, if any, that a change to the Biomarkers for Oncology LCD would have on the coverage and related revenue of Ova1, and such impact may be material to our business, results of operations and financial condition. We are monitoring developments closely and believe additional due process would be required if the activities contemplated by Novitas change the coverage determination for Ova1.

***Failure to expand commercial, Medicare or Medicaid coverage for Ova1Plus and OvaWatch.***

The Company has implemented strategies to expand payer coverage for its ovarian cancer risk assessments, including securing coverage for OvaWatch that is consistent with existing coverage for Ova1Plus. There can be no assurances that the Company will be able to secure additional payer coverage for Ova1Plus, nor can there be assurances that comparable coverage will be available for OvaWatch. Failure to expand payer coverage may have a significant negative impact on product adoption and our results of operations.

***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, exercise of common stock warrants, 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 or more 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 December 31, 2022, we had 124,594,888 shares of our common stock outstanding and 3,576,486 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 9,828,424 shares of our common stock that were subject to outstanding options. In addition, as of December 31, 2022, warrants to purchase 12,000,000 shares of our common stock were outstanding. These warrants are exercisable at the election of the holders thereof, in accordance with the terms of the related Form of Warrant, at an average exercise price of \$0.88 per share.

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

***We have increased our authorized shares for issuance which could cause significant dilution.***

As discussed in "Risks Related to our Business and Industry," our management believes the successful achievement of our business objectives may require additional financing through one or a combination of the issuance of common stock in public or private equity offerings, debt financings, exercise of common stock warrants, collaborations, licensing arrangements, grants and government funding and strategic alliances.

To effectuate that, we sought and obtained authorization from stockholders to increase our authorized shares by 50,000,000 for a total of 200,000,000, for issuance on February 6, 2023. Such an increase may be dilutive to stockholders, and further may affect the prevailing trading prices of our common stock.

***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, *de novo* classification or 510(k) clearance of LDTs, it has generally chosen not to enforce those requirements to date. Separately, the Centers for Medicare & Medicaid Services oversees clinical laboratory



operations through the CLIA program. FDA has indicated that it may seek to increase its regulation of LDTs. Any future rulemaking, guidance, or other oversight of LDTs and clinical laboratories that develop and perform them, if and when finalized, may affect the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws.

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 June 2021, Congress introduced legislation called the Verifying Accurate, Leading-edge IVCT Development Act (the "VALID Act"), which would have established a new risk-based regulatory framework for *in vitro* clinical tests ("IVCTs"), a category which would have included IVDs, LDTs, collection devices and instruments used with such tests. This legislation was not enacted during that session of Congress, but could be introduced again in the future.

In the meantime, the regulation by the FDA of our tests that are positioned as LDTs remains uncertain. If FDA premarket clearance, *de novo* classification 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.

It is unclear how FDA will apply the guidance document to our current software and to software that we may develop in the future. It is also unclear whether FDA will apply the final guidance to CDS software that is used by clinical laboratories as part of an LDT, since LDTs have historically been subject to FDA enforcement discretion.

***We may not succeed in improving existing or 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 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 platform such as 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.

Our failure to achieve the intended development outcome either ourselves or through a collaboration may result in an impact to our commercial success of the EndoCheck or other product launches.

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 a 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 serial monitoring, 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 advisory panels. 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, can take 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 our OvaSuite products and Aspira Synergy platform will depend on many factors, including:

- our ability to drive adoption of our products;
- our success in establishing new clinical practices or changing previous ones;
- 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 may impact patients' willingness to pay for our products and may 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 OvaSuite and developing future diagnostic products.

In October 2022, we announced the launch of a comarketing arrangement for Ova1Plus with BioReference Laboratories. Under terms of the agreement, the Aspira and BioReference sales teams will collaborate to sell Ova1Plus to gynecologists and other women's healthcare providers nationwide. If we are unable to collaborate successfully, it may affect our ability to improve adoption of our Ova1Plus test or to successfully secure additional commercial collaborations.

***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 OvaSuite 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 OvaSuite products will be adversely affected.

Competitive offerings include Fujirebio Diagnostics' FDA cleared 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 OvaSuite products 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 and software 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 granted a request for 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 and analytical data, as well as extensive information regarding software. 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.

Certain of our software algorithms have been authorized for marketing by FDA as part of our cleared or *de novo* classified tests. If any of the software that we use in our LDTs or that we make available to third parties is determined by FDA to be non-exempt clinical decision support software, this could impede our ability to offer our tests or distribute our software to third parties and we could incur substantial costs and delays associated with trying to obtain premarket 510(k) clearance, *de novo* classification, or premarket review and incur costs associated with complying with post-market controls.

***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, 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 OvaSuite products.***

The commercialization of our OvaSuite tests depends 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 OvaSuite 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 OvaSuite 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, 2022 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 restrict our ability to use our NOL carryforwards to offset taxable income due to ownership change limitations that have occurred 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 2023 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 2023 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 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 previous years, 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. There is no assurance that sales or collections will not be adversely affected by new outbreaks of COVID-19 or other health epidemics.

#### **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 any 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.

***Certain of our patent registrations will expire, which may cause us to have significant competition.***

Our success depends in part on our ability to own and assert our patent registrations to maintain and enforce our proprietary rights, including defending against infringement actions. We have some patent registrations covering biomarkers that may be expiring, and our strategy to continue to seek protection and file patent applications may or may not result in additional patents being issued.

If any such patent registration is no longer protectable and could be exploited by a competitor, it could have a material adverse effect on our business, consolidated results of operations and financial condition.

## **RISKS RELATED TO OWNING OUR STOCK**

***We have identified two material weaknesses in our internal control over financial reporting. If we are unable to remediate the material weaknesses, or if we experience additional material weaknesses or other deficiencies in the future, or otherwise fail to maintain an effective system of internal control over financial reporting, then these material weaknesses could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting 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 management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation of those internal controls. A material weakness is a deficiency, or a combination of deficiencies over information systems and a lack of timely execution of certain internal controls over financial reporting and disclosures.

Management evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. Management concluded that our disclosure controls and procedures were not effective as of December 31, 2022, due to two material weaknesses in the internal control over financial reporting related to multiple design deficiencies and a lack of a timely operation of certain internal controls over financial reporting and disclosures.

Internal controls related to the operation of technology systems are critical to maintaining adequate internal control over financial reporting. As disclosed in Part II, Item 9A, management identified a material weakness in the design and operation of internal control related to information technology general controls (ITGCs) due to the lack of timely identification of certain information technology (IT) systems that are hosted by third-party service organizations and are used to process and record certain revenue and expense transactions and support our financial reporting processes resulting in the lack of certain internal controls over these IT systems and over data and reports accumulated in such IT systems. Additionally, management identified a material

weakness in the design and operation of certain internal controls over financial reporting that were not performed timely in connection with the year-end close and reporting process to ensure the completeness and accuracy of the consolidated financial statements.

While there can be no assurance that our efforts will be successful, we plan to remediate the material weaknesses during fiscal 2023. Our ability to comply with the annual internal control report requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company. To effectively manage our IT environment and financial reporting environment, we will need to continue to improve our operational, financial, and management controls, and our reporting systems and procedures.

The above material weaknesses did not result in a misstatement; however, they could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected. To remediate the material weakness in internal control over financial reporting related to the design of controls for system implementations, we have and will continue to update the design and review of controls for system implementations, continue to leverage internal expertise in systems implementation for the design of controls, and work with qualified external advisors to support these efforts. To remediate the material weakness in internal control over financial reporting related to timely evaluation of the accounting treatment and disclosure of our contracts, we have and will continue to implement new procedures and testing for review of our accounting treatment of contracts. We intend to continue to take steps to remediate the material weaknesses.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by The Nasdaq Stock Market, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

***The liquidity and trading volume of our common stock may be low, and our ownership is concentrated, which could adversely impact the trading price of our common stock and our stockholders' ability to obtain liquidity.***

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 December 30, 2021, January 13, 2022, February 14, 2022, February 16, 2022 and February 15, 2023, we estimate that a total of five persons beneficially own approximately 45.0% of our outstanding common stock. Under the May 2013 stockholders agreement, one of our stockholders has the right to designate a director to be nominated by us to serve on our Board of Directors, and t stockholder has exercised this right.

In addition, a Stockholders Agreement we entered into in connection with a May 2013 private placement gives two of the primary investors in that private placement the right to participate in future equity offerings, including the offering of common stock being made pursuant to this prospectus supplement, on the same terms as other investors. In addition, the Stockholders Agreement prohibits us from taking certain material actions without the consent of one of the primary investors in the May 2013 private placement. These material actions include:

- making any acquisition with a value greater than \$2 million;
- offering, selling or issuing securities senior to our common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to our common stock;
- 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.

As a result of the foregoing, a limited number of 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. In addition, the interests of the parties to the Stockholders Agreement could conflict with or differ from 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, 2022, the closing trading price of our common stock ranged from a high of \$1.81 per share to a low of \$0.30 per share. During the three months ended December 31, 2022, the closing trading price of our common stock ranged from a high of \$0.41 per share to a low of \$0.30 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 OvaSuite 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;
- our ability to continue as a going concern;
- 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.

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

## **OPERATIONAL 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.

***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, foreign or domestic conflicts, epidemics or pandemics such as the COVID-19 pandemic, 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:

discontinued vendor support of legacy systems;  
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 HIPAA of 1996 as amended by HITECH. 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, 2024
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

#### Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "AWH."

#### Holders of Common Stock

On March 20, 2023, there were 77 registered holders of record of our common stock. The closing price of our common stock on March 20, 2023 was \$0.39.

#### 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.

#### Recent Sales of Unregistered Securities

None.

#### Issuer Purchases of Equity Securities

None.

#### 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 Aspira Women's Health 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, 2022, options to purchase 4,306,561 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, 2022, options to purchase 5,521,863 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, 2022, were as follows:

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Shares Reflected in First Column)</b>
Equity compensation plans approved by security holders	9,828,424	\$ 1.95	3,576,486
Equity compensation plans not approved by security holders	-	-	-
Total	<u>9,828,424</u>		<u>3,576,486</u>

#### Stock 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-25 of this Annual Report on Form 10-K, and "Risk Factors", which are discussed in Item 1A. The statements below contain forward-looking statements based upon current plans, expectations, and beliefs that involve risks and uncertainties. See "Forward-Looking Statements" on page 1 of this Annual Report on Form 10-K.*

### Overview

Our core mission is to transform women's gynecologic health through the development of technology-enabled diagnostic tools, 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.

We plan to broaden our focus to the differential diagnosis of other gynecologic diseases that typically cannot be assessed through traditional non-invasive clinical procedures. We expect to continue commercializing our existing and new technology and to distribute our tests through our decentralized technology transfer service platform, Aspira Synergy. We also intend to continue to raise public awareness regarding the diagnostic superiority of Ova1Plus as compared to cancer antigen 125 ("CA-125") on its own for all women, but especially for racially diverse women with adnexal masses, as well as the superior performance of machine learning algorithms in detecting ovarian cancer in different racial and ethnic populations. We plan to continue to expand access to our tests among Medicaid patients as part of our corporate mission to make the best care available to all women, and we plan to advocate for legislation and the adoption of our technology in professional society guidelines to provide broad access to our products and services.

We are focused on commercializing our products and have 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 2023, we plan to continue our efforts to commercialize Ova1Plus by utilizing select partnerships for distribution and expanding our managed care coverage and contracts in select markets.

We plan to develop additional diagnostic algorithms utilizing proteins and molecular markers 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. OvaWatch, our first series of LDT algorithms was designed to be launched in two phases. We launched the first phase in the fourth quarter of 2022 as a single use point in time test. Phase II, which is planned to be launched in 2023 upon obtaining sufficient data from the ongoing prospective serial monitoring clinical study, has been designed to improve the effectiveness of ongoing monitoring of lower risk adnexal masses. We believe the patient population for the single-use product is three or more times greater than the patient population for Ova1Plus and that the serial monitoring test may exponentially expand that larger patient application.

We expect that our second diagnostic algorithm, EndoCheck, will be an aid in the diagnosis of endometriosis, and is planned for launch in the second half of 2023.

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.

### Liquidity and Capital Resources

We plan to continue to expend resources selling and marketing OvaSuite and Aspira Synergy and developing additional diagnostic tests and service capabilities.

We do not believe our existing cash and cash equivalents balance and cash flow from operations will be sufficient to meet our working capital, capital expenditures, and material cash requirements from known contractual obligations for the next twelve months and beyond. Our future capital requirements, the adequacy of available funds, and cash flows from operations could be affected by various risks and uncertainties, including, but not limited to, those detailed in Part I, Item 1A, Risk Factors in this Annual Report. 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 \$498.9 million as of December 31, 2022. We also expect to incur a net loss and negative cash flows from operations for 2023. In order to continue our operations as currently planned through 2023 and beyond, we will need to raise additional capital. Given the above conditions, there is substantial doubt about the Company's ability to

continue as a going concern. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

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. We were able to achieve the 25 full-time employee milestone. However, the Company has not yet been legally released of the liability and the achievement of the milestone is subject to lender review and approval. If we were 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 6 of our consolidated financial statements.

As discussed in Note 6 to the consolidated financial statements, as of December 31, 2022, we are engaged in two lease agreements. Our Austin, Texas lease renewal agreement has a term of 12 months and expires on January 31, 2024, with no automatic renewal or renewal option. Our Trumbull, Connecticut lease renewal agreement has five-year term and expires on June 30, 2026, with a five-year renewal option.

As discussed in Note 6 to the consolidated financial statements, on May 1, 2020, we obtained a 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, 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.

As discussed in Note 1 to the consolidated financial statements, on June 1, 2022, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that, for the preceding 30 consecutive business days, the closing bid price for Aspira common stock was below the minimum \$1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a) (2). On November 29, 2022, we were granted an additional 180-calendar day compliance period, or until May 29, 2023, to regain compliance with the minimum bid price requirement. We may achieve compliance during this period if the closing bid price of Aspira common stock is at least \$1.00 per share for a minimum of 10 consecutive business days. There is no assurance that we will be able to regain compliance by the May 29, 2023 extended deadline, and there is no assurance that we will otherwise maintain compliance with this or any of the other Nasdaq continued listing requirements.

As discussed in Note 7 to the consolidated financial statements, on August 22, 2022, the Company completed a public offering (the "2022 Offering") resulting in net proceeds of approximately \$7,675,000, after deducting underwriting discounts and offering expenses of \$1,325,000.



As discussed in Note 12 to the consolidated financial statements, on February 10, 2023, Aspira Women's Health Inc. entered into a Controlled Equity Offering Sales Agreement, (the "Sales Agreement"), with Cantor Fitzgerald & Co., ("Cantor"), as agent, pursuant to which we may offer and sell, from time to time, through Cantor, shares of our common stock, par value \$0.001 per share, having an aggregate offering price of up to \$12.5 million, or the Placement Shares.

On March 28, 2023, we entered into an agreement, (the "LPC Agreement") with Lincoln Park Capital Fund LLC ("Lincoln Park"), pursuant to which we have the right to sell to Lincoln Park shares of our common stock, having an aggregate value of up to \$10 million, subject to certain limitations and conditions, at our sole discretion during a 36-month period ending March 27, 2026.

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. We believe that the rights of one of the primary investors have so terminated.

As mentioned, the Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2022 we had an accumulated deficit of \$498.9 million and stockholders' equity of \$6.7 million. As of December 31, 2022, we had \$13.3 million of cash and cash equivalents (excluding restricted cash of \$251,000), and \$5.8 million of current liabilities. Working capital was \$10.5 million at December 31, 2022. 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 2023.

We expect to incur a net loss and negative cash flows from operations in 2023.

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 OvaSuite product adoption by physicians and patients;
- the rate of product adoption by healthcare systems and large physician practices of the decentralized distribution agreements for OvaSuite;
- 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.

In the event that our existing cash on hand is not sufficient to fund our near or long term operations, meet our capital requirements or satisfy our anticipated obligations as they become due, we expect to take further action to protect our 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.

## Results of Operations - Year Ended December 31, 2022 as compared to Year Ended December 31, 2021

The Company's selected summary financial and operating data for the years ended December 31, 2022 and 2021 were as follows:

(dollars in thousands)	Year Ended December 31,		Increase (Decrease)	
	2022	2021	Amount	%
Revenue:				
Product	\$ 7,970	\$ 6,568	\$ 1,402	21
Genetics	214	244	(30)	(12)
Total revenue	8,184	6,812	1,372	20
Cost of revenue:				
Product	3,698	3,016	682	23
Genetics	167	734	(567)	(77)
Total cost of revenue	3,865	3,750	115	3
Gross profit	4,319	3,062	1,257	41
Operating expenses:				
Research and development	5,953	5,314	639	12
Sales and marketing	14,948	17,086	(2,138)	(13)
General and administrative	16,183	13,257	2,926	22
Total operating expenses	37,084	35,657	1,427	4
Loss from operations	(32,765)	(32,595)	(170)	1
Change in fair value of warrant liabilities	5,472	-	5,472	-
Interest income (expense), net	17	(48)	65	(135)
Other income, net	106	981	(875)	(89)
Net loss	<u>\$ (27,170)</u>	<u>\$ (31,662)</u>	<u>\$ 4,492</u>	<u>(14)</u>

**Product Revenue.** Product revenue was \$7,970,000 for the year ended December 31, 2022, compared to \$6,568,000 for the same period in 2021. 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 21% product revenue increase is due to an increase in OvaSuite test volume compared to the prior year.

The number of OvaSuite tests performed increased 23% to approximately 21,423 Ova1Plus tests during the year ended December 31, 2022 compared to approximately 17,377 OvaSuite tests for the same period in 2021. The volume increase was primarily due to our focused commercialization investment.

The revenue per OvaSuite test performed decreased from approximately \$378 in 2021 to approximately \$372 in 2022. Although there was a volume increase in tests performed, there was a shift in the payer mix toward tests performed for lower-revenue-per-test-performed payers, such as those for Medicaid.

**Genetics Revenue.** Genetics revenue was \$214,000 for the year ended December 31, 2022, compared to \$244,000 for the same period in 2021. Revenue for Aspira GenetiX was recognized when the Aspira GenetiX test was completed based on estimates of what we expect to ultimately realize.

The number of genetics tests performed decreased 32% to approximately 342 Aspira GenetiX tests during the year ended December 31, 2022 compared to approximately 505 Aspira GenetiX tests for the same period in 2021. The volume decrease was primarily due to the wind down of our genetics testing line of business. The Company has discontinued the genetics testing offering effective September 30, 2022.

**Cost of Revenue - Product.** Cost of product revenue was \$3,698,000 for the year ended December 31, 2022 compared to \$3,016,000 for the same period in 2021, representing an increase of \$682,000, or 23%, 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 \$167,000 for the year ended December 31, 2022 compared to \$734,000 for the same period in 2021, representing a decrease of \$567,000, or 77%, due primarily to the discontinuing of this service in September 2022.

**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, 2022 increased by \$639,000, or 12%, compared to the same period in 2021. This increase was primarily due to approximately \$868,000 of costs related to our sponsored research collaboration agreements, increases in employment related expenses of \$143,000, partially offset by a decrease in lab supplies and clinical trials of \$271,000 and a decrease in consulting expenses of \$107,000. Included in employment costs, there was severance paid in relation to our commercial reorganization and job eliminations of \$166,000. We expect research and development expenses to increase in 2023, 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. 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, 2022 decreased by \$2,138,000, or 13%, compared to the same period in 2021. This decrease was primarily due to decreased employment related expenses of \$1,644,000, consulting costs of \$330,000 and other marketing expenses of \$802,000, offset by a \$534,000 increase to travel and a \$104,000 increase to health economic studies. Included in employment costs, there was severance paid in relation to our commercial reorganization and job eliminations of \$560,000. We expect sales and marketing expenses to decrease in 2023, due to recent personnel changes.

**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, 2022 increased by \$2,926,000, or 22%, compared to the same period in 2021. This increase was primarily due to the insourcing and expansion of corporate functions such as HR, IT and legal, as well as the addition of the Executive Chair position, which increased personnel related expenses by \$2,206,000, as well as increased accounting costs of \$209,000 and issuance costs associated with issuance of warrants of \$1,117,000 (see Note 7 to the consolidated financial statements), offset by decreased outside legal costs of \$639,000. Included in employment costs, there was severance of \$205,000. We expect general and administrative expenses to decrease in 2023 due to recent personnel changes.

**Interest Income (Expense, net).** The Company had net interest expense of \$48,000 for the year ended December 31, 2021 and \$17,000 in net interest income for the year ended December 31, 2022. The change in the net balance from interest expense to interest income was primarily due to an increase in the interest rate applied to our money market accounts.

**Other Income, net.** Other income for the year ended December 31, 2022 decreased by \$875,000, compared to the same period in 2021. The decrease 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, offset by the recognition of a \$119,000 grant received from the Israel - U.S. Binational Industrial R&D Foundation.

**Cash Flows** The following table summarizes the Company's cash flows for the periods ended December 31, 2022 and 2021.

Cash Flows				
The following table summarizes the Company's cash flows for the periods ended December 31, 2022 and 2021:				
	Year Ended December 31,			
	2022		2021	
	(in thousands)			
Cash used in operating activities	\$	32,185	\$	27,395
Cash used in investing activities	\$	232	\$	184
Cash provided by financing activities	\$	8,544	\$	48,378

Net cash used in operating activities was \$32,185,000 for the year ended December 31, 2022, resulting primarily from the net loss reported of \$27,170,000, changes in fair value of warrant liabilities in the amount of approximately \$5,472,000 and

changes in accounts payable, accrued and other liabilities of \$2,224,000, primarily offset by expenses in the amount of \$2,676,000 related to stock compensation expense.

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 investing activities was \$232,000 and \$184,000 for the years ended December 31, 2022 and 2021, respectively, which consisted primarily of property and equipment purchases.

Net cash provided by financing activities was \$8,544,000 for the year ended December 31, 2022, which resulted primarily from the 2022 Offering, resulting in net proceeds to the Company of approximately \$7,675,000 after deducting underwriting discounts and offering expenses, including \$1,117,000 of expenses attributed to warrants that were included in the net loss. 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.

We have significant NOL carryforwards as of December 31, 2022 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 restrict our ability to use our NOL credit carryforwards due to ownership change limitations that have occurred 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 2023 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 2023 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 is restricted due to ownership change limitations that have occurred in the past or that could occur in the future, as required by Section 382, as well as similar state specific provisions.

Our management believes that Section 382 ownership changes most recently occurred as a result of our follow-on public offerings in 2011 and 2013. These ownership changes may also limit the amount of NOL carryforwards from periods prior to Section 382 ownership changes that can be utilized annually to offset taxable income in years after the ownership changes.

These limitations may result in the expiration of a portion of the NOL carryforwards before utilization. The amount of current NOL carryforwards that are going to be forced to expire prior to utilization as a result of such limitations have been removed from gross deferred tax assets. Due to the existence of a full valuation allowance against remaining NOLs that can still potentially be utilized, it is not expected that Section 382 limitations will have an impact on our results of operations or financial position.

### **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 OvaSuite or Aspira GenetiX tests 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 are subject to uncertainty and require significant judgment by management because of the various inputs of the factors considered. 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.

There is inherent uncertainty in our forecasts and projections and, if we had made different assumptions and estimates than those described previously, the amount of our stock-based compensation expense, net loss and net loss per common stock amounts could have been materially different.

#### Liquidity

As discussed in Note 7 to the consolidated financial statements, we have incurred significant net losses and negative cash flows from operations since inception, and as a result have an accumulated deficit of approximately \$498,898,000 at December 31, 2022. We expect to incur a net loss in 2023 as well. In order to continue our operations as currently planned through 2023 and beyond, we will need to raise additional capital. Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

#### **Recent Accounting Pronouncements**

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

#### **Recent Developments**

##### ***Leadership Updates***

Effective January 4, 2022, Minh Merchant was appointed as the Company's General Counsel & Secretary.

On February 23, 2022, Valerie B. Palmieri was appointed as the Company's Executive Chairperson effective March 1, 2022, and stepped down as its President and Chief Executive Officer.

On February 24, 2022, Nicole Sandford was appointed as the Company's President and Chief Executive Officer, effective March 1, 2022.

Effective July 5, 2022, Ryan Phan was appointed as the Company's Chief Operating & Scientific Officer.

On November 30, 2022, Robert Beechey, the Company's Chief Financial Officer, resigned.

Effective December 1, 2022, Marlene McLennan was appointed as the Company's Interim Chief Financial Officer.

## **Business, Product and Coverage Updates**

### **Government Strategy Updates**

The 2023 Federal Omnibus bill includes language that requires CMS to develop a plan within 180 days to develop a National Coverage Determination that will cover multi-marker testing for ovarian cancer for all patients covered by Medicare. It is expected that this language will include both Ova1 and OvaWatch. This bill was the result of extensive collaboration with numerous women's advocacy groups and legislators, particularly Rosa DeLauro, the head of the Appropriations Committee.

### **Coverage Updates**

On January 5, 2022, we were credentialed by Medicaid for coverage in Washington.

On April 22, 2022, we added Medicaid coverage for Minnesota.

On August 5, 2022, we added coverage for Medicaid patients in Virginia.

On August 22, 2022, we received Medicaid credentialing for Pennsylvania.

On August 24, 2022, we added Medicaid coverage for patients in Rhode Island.

On September 30, 2022, we added Medicaid coverage for Alabama.

On December 30, 2022, we were credentialed by Colorado Medicaid.

With the addition of these plans, we are now credentialed to provide services to a total of 64 million Medicaid lives, or 80% of the Medicaid population.

In February 2023, a major global commercial payer agreed to cover OvaWatch effective on April 1, 2023.

### **Abstract / Study Updates**

On June 16, 2022, the Company announced the online publication of a paper entitled "*Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer*," in the June issue of JCO Clinical Cancer Informatics. The paper validates the OvaWatch algorithm in the detection of ovarian cancer and demonstrates the potential of OvaWatch in accurately assessing the risk of ovarian malignancy in patients with pelvic masses. Ovarian cancer is the deadliest gynecologic cancer, with most cases being diagnosed at late stage. Early detection of ovarian cancer is key to helping to reduce mortality; however, other current non-invasive risk assessment measures on the market vary in their usefulness.

On September 2022, the Company announced publication of a study, "*Clinical Performance of a Multivariate Index Assay in Detecting Early-Stage Ovarian Cancer in Filipino Women*," in the peer-reviewed International Journal of Environmental Research and Public Health. The study concluded that incorporating MIA2G (OVERA) rather than CA-125 into clinical assessment would increase the detection of early-stage ovarian cancers, regardless of menopausal status.

On January 6, 2023, the Company announced its manuscript, entitled: "Validation of Deep Neural Network-based Algorithm Supporting Clinical Management of Adnexal Mass," has been published in the prestigious peer-reviewed journal, Frontiers in Medicine. The paper presents findings from the multi-site clinical study of the company's new assay, OvaWatch, describing real-world evidence supporting the use of OvaWatch for the clinical management of adnexal masses.

### **Collaboration Updates**

On March 25, 2021, we announced that we entered into an agreement with Harvard Dana-Farber Cancer Institute, Brigham & Women's Hospital and Medical University of Lodz to evaluate their jointly developed novel microRNA ("miRNA") technology in combination with current Aspira technologies, for the development of a highly sensitive and specific early detection test for women with ovarian cancer. The Phase 1 Proof of Concept evaluation surpassed all required metrics and based on the outcome data, in 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. The Phase II collaboration will begin in 2023.

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. However, following the cancellation of our agreement with Axia Women's Health to provide genetics testing on our Aspira Synergy platform and our decision to discontinue our genetics offerings in September 2022, the Company canceled this agreement.

On August 8, 2022, the Company entered into a sponsored research agreement with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz for the generation of a multi-omic, non-invasive diagnostic aid to identify endometriosis based on circulating miRNAs and proteins. This collaboration is expected to accelerate the Company's development and commercialization of future endometriosis products, such as EndoCheck. Under the terms of and as further described in the agreement, payments of approximately \$1,252,000 have or will become due from the Company to the counterparties upon successful completion of certain deliverables in 2022 and 2023 as follows: 68% was paid in August 2022, 15% will become payable upon completion of certain deliverables estimated to occur in the first quarter of 2023, and 17% will become payable upon completion of certain deliverables estimated to occur in the second quarter of 2023. As of December 31, 2022 approximately \$868,000 has been recorded as expense for the project.

#### **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. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our consolidated financial statements, including consolidated balance sheets as of December 31, 2022 and 2021, consolidated statements of operations for the years ended December 31, 2022 and 2021, consolidated statements of changes in stockholders' equity for the years ended December 31, 2022 and 2021, consolidated statements of cash flows for the years ended December 31, 2022 and 2021 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-25.

#### **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 Interim 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, 2022.

Based on that evaluation, our Chief Executive Officer and Interim Chief Financial Officer have concluded that as of December 31, 2022, our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15(d)-15(e) under the Exchange Act, were not effective.

Following the identification of the material weaknesses described below and prior to filing this Annual Report, we completed substantive procedures for the year ended December 31, 2022. Based on these procedures, management concluded that the Company's financial statements included in this Annual Report have been prepared in accordance with generally accepted accounting principles. Our Chief Executive Officer and Interim Chief Financial Officer have certified that, based on their knowledge, the financial statements, and other financial information included in this Annual Report, present fairly in all material

respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this Annual Report.

### **Management's Annual Report on Internal Control over Financial Reporting**

We are responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2022. 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.

We did not design general information technology controls, including user access and program change-management controls, nor did we adequately assess the controls of service organizations related to certain information technology systems that are used to process and record certain revenue and expense transactions and support the Company's financial reporting processes or over data and reports accumulated in such information technology systems. Additionally, certain internal controls over financial reporting that ensure the completeness and accuracy of the consolidated financial statements were not performed timely in connection with the year-end close and reporting process. These have resulted in material weaknesses in our internal control over financial reporting as of December 31, 2022. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As a result, our management concluded that as of December 31, 2022, our internal control over financial reporting was not 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, 2022 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.

### **Remediation Activities**

In order to address the material weaknesses in internal control over financial reporting described above, management intends to perform, with direction from the audit committee, the following remediation activities:

Retain an internal controls specialist to complement the skills of the existing accounting and financial reporting staff.  
Complete a preliminary process to identify all information technology applications that support the Company's financial reporting processes and assess the risk of misstatement associated with each.  
Plan a comprehensive review of the design and performance of internal controls related to information technology applications, including user access and program change controls.  
Enhance controls that require the assessment of service organization controls prior to implementation and on an annual basis.  
Implement additional consultation requirements for new contracts that involve information technology applications to ensure internal controls are designed and implemented at the time of integration.  
Enhance procedures designed to annually review of the materiality of transactions that are processed by applications implemented in prior years to identify programs that have become material subsequent to their initial implementation.



Review timelines within our documented disclosure controls and procedures and adjust dates accordingly.  
Retain additional accounting and financial reporting resources during the year end close to improve our ability to perform our disclosure controls and procedures on a timely basis.  
Provide additional training and continuing education to accounting staff regarding SEC requirements and required disclosures under generally accepted accounting principles.

Management will continue to review and make necessary changes to the overall design of our internal control environment, as well as policies and procedures to improve the overall effectiveness of internal control over financial reporting. The material weaknesses will not be considered remediated, however, until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

***Limitations on Effectiveness of Controls and Procedures and Internal Control over Financial Reporting***

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

***Changes in Internal Control over Financial Reporting***

Other than the material weaknesses described above, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information regarding the Company's directors, committees of the Company's Board of Directors, the Company's director nomination process, and the Company's executive officers appearing under the heading "Election of Directors," "Corporate Governance," "Management", "Security Ownership of Certain Beneficial Owners and Management" and "Delinquent Section 16(a) Reports" of the Company's proxy statement relating to our annual meeting of stockholders to be held in 2023 (the "2023 Proxy Statement") is incorporated by reference.

The Company has adopted a Code of Business Conduct and Ethics for its directors, officers (including its principal executive officer, principal financial officer and principal accounting officer) and employees. The Company's Code of Business Conduct and Ethics is available on the Company's website at [ir.aspirawh.com/corporate-governance](http://ir.aspirawh.com/corporate-governance). Within the time period required by the SEC and Nasdaq, we will post on the Company's website at [ir.aspirawh.com/corporate-governance](http://ir.aspirawh.com/corporate-governance) any amendment to the Company's Code of Business Conduct and Ethics or any waivers of such provisions granted to executive officers and directors.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information appearing under the headings "Board Compensation," and "Executive Officer Compensation," of the 2023 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 2023 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 2023 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 2023 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-25.

2. *Financial Statement Schedules*

All financial statement schedules have been omitted as the information is not required under the related instructions or is not applicable or because the information required is already included in the financial statements or the notes to those financial statements.

## (b) EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
Form	File No.	Exhibit	Filing Date			
8-K	000-31617	3.1	January 25, 2010			
10-Q	001-34810	3.2	August 14, 2014			
8-K	001-34810	3.1	June 11, 2020			
8-K	001-34810	3.1	February 7, 2023			
8-K	001-34810	4.1	April 17, 2018			
8-K	001-34810	3.1	February 28, 2022			
S-1/A	333-32812	4.1	August 24, 2000			
8-K	001-34810	10.1	May 14, 2013			
8-K	001-34810	10.2	May 14, 2013			
10-K	001-34810	4.4	April 7, 2020			
10-K	001-34810	4.5	April 7, 2020			
S-3	333-252267	4.7	January 20, 2021			
10-K	001-34810	4.7	March 31, 2022			
8-K	001-34810	4.1	August 24, 2022			
8-K	001-34810	10.1	March 30, 2023			
8-K	001-34810	10.2	March 30, 2023			
8-K	000-31617	10.1	February 12, 2010			
S-1/A	333-32812	10.9	August 24, 2000			
8-K	001-34810	10.1	December 17, 2013			
8-K	001-34810	10.1	June 22, 2015			
8-K	001-34810	10.1	June 27, 2018			
10-K	001-34810	10.7	March 28, 2019			
10-Q	001-34810	10.1	August 10, 2022			
10-Q	001-34810	10.4	August 10, 2022			

<a href="#"><u>10.9</u></a>	<a href="#"><u>Form of Vermillion, Inc.'s Restricted Stock Award #</u></a>	10-K	001-34810	10.8	March 28, 2019
<a href="#"><u>10.10</u></a>	<a href="#"><u>Form of Vermillion, Inc. Restricted Stock Award Agreement #</u></a>	10-Q	001-34810	10.2	August 10, 2022
<a href="#"><u>10.11</u></a>	<a href="#"><u>Form of Aspira Women's Health Inc Restricted Stock Award Agreement #</u></a>	10-Q	001-34810	10.5	August 10, 2022
<a href="#"><u>10.12</u></a>	<a href="#"><u>Aspira Women's Health Inc. 2019 Stock Incentive Plan #</u></a>	10-Q	001-34810	10.3	August 10, 2022
<a href="#"><u>10.13</u></a>	<a href="#"><u>Form of Vermillion, Inc. Stock Option Award Agreement (non-employee) #</u></a>	10-Q	001-34810	10.6	August 10, 2022
<a href="#"><u>10.14</u></a>	<a href="#"><u>Form of Aspira Women's Health Inc. Stock Option Award Agreement (non-employee) #</u></a>	10-Q	001-34810	10.7	August 10, 2022
<a href="#"><u>10.15</u></a>	<a href="#"><u>Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Valerie B. Palmieri, effective March 1, 2022 # †</u></a>	8-K	001-34810	10.1	February 28, 2022
<a href="#"><u>10.16</u></a>	<a href="#"><u>Testing and Services Agreement between Vermillion, Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated, dated as of March 11, 2015</u></a>	10-Q	001-34810	10.5	May 12, 2015
<a href="#"><u>10.17</u></a>	<a href="#"><u>Amendment No. 1 to the Testing and Services Agreement between Vermillion, Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated dated April 10, 2015</u></a>	10-Q	001-34810	10.6	May 12, 2015
<a href="#"><u>10.18</u></a>	<a href="#"><u>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</u></a>	8-K	001-34810	10.1	March 13, 2017
<a href="#"><u>10.19</u></a>	<a href="#"><u>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</u></a>	8-K	001-34810	10.1	March 6, 2018
<a href="#"><u>10.20</u></a>	<a href="#"><u>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</u></a>	8-K	001-34810	10.1	March 17, 2020
<a href="#"><u>10.21</u></a>	<a href="#"><u>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</u></a>	10-Q	001-34810	10.1	May 16, 2016
<a href="#"><u>10.22</u></a>	<a href="#"><u>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</u></a>	10-Q	001-34810	10.3	May 16, 2016
<a href="#"><u>10.23</u></a>	<a href="#"><u>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</u></a>	10-Q	001-34810	10.4	May 16, 2016
<a href="#"><u>10.24</u></a>	<a href="#"><u>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</u></a>	10-K	001-34810	10.21	March 13, 2018
<a href="#"><u>10.25</u></a>	<a href="#"><u>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</u></a>	10-K	001-34810	10.22	April 7, 2020
<a href="#"><u>10.26</u></a>	<a href="#"><u>Promissory Note, dated May 1, 2020, between Vermillion, Inc. and BBVA USA</u></a>	8-K	001-34810	10.1	May 7, 2020
<a href="#"><u>10.27</u></a>	<a href="#"><u>Consulting Agreement, dated March 25, 2021, by and between David Schreiber and Aspira Women's Health Inc. #</u></a>	10-Q	001-34810	10.1	May 14, 2021
<a href="#"><u>10.28</u></a>	<a href="#"><u>Employment Agreement between Aspira Women's Health Inc. and Nicole Sandford effective March 1, 2022 # †</u></a>	8-K	001-34810	10.2	February 28, 2022
<a href="#"><u>10.29</u></a>	<a href="#"><u>Consulting Agreement between Aspira Women's Health Inc. and Robert Beechey dated November 10, 2022 #</u></a>	10-Q	001-34810	10.3	November 10, 2022
<a href="#"><u>10.30</u></a>	<a href="#"><u>Employment Agreement between Aspira Women's Health Inc. and Marlene McLennan, effective December 1, 2022#</u></a>	8-K	001-34810	10.1	November 30, 2022
<a href="#"><u>10.31</u></a>	<a href="#"><u>Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Nicole Sandford effective March 1, 2023# †</u></a>	8-K	001-34810	10.1	March 2, 2023
<a href="#"><u>10.32</u></a>	<a href="#"><u>Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Minh Merchant, effective March 28, 2023#†</u></a>				√

<a href="#">10.33</a>	<a href="#">Employment Agreement between Aspira Women's Health Inc. and Dr. Ryan Phan, effective May 3, 2022</a>					✓
<a href="#">10.34</a>	<a href="#">Sales Agreement between Aspira Women's Health Inc. and Cantor Fitzgerald &amp; Co., dated February 10, 2023</a>	8-K	001-34810	1.1	February 10, 2023	
<a href="#">21.0</a>	<a href="#">Subsidiaries of Registrant</a>	10-K	001-34810	21.0	March 31, 2022	
<a href="#">23.1</a>	<a href="#">Consent of BDO USA, LLP, Independent Registered Public Accounting Firm</a>					✓
<a href="#">31.1</a>	<a href="#">Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>					✓
<a href="#">31.2</a>	<a href="#">Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>					✓
<a href="#">32.1</a>	<a href="#">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</a>					✓
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

# 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**

	<b><u>Page No.</u></b>
<a href="#">Report of Independent Registered Public Accounting Firm (BDO USA, LLP; Woodbridge, New Jersey; PCAOB ID#243)</a>	<a href="#">F-1</a>
<a href="#">Consolidated Balance Sheets at December 31, 2022 and 2021</a>	<a href="#">F-3</a>
<a href="#">Consolidated Statements of Operations for the years ended December 31, 2022 and 2021</a>	<a href="#">F-4</a>
<a href="#">Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2022 and 2021</a>	<a href="#">F-5</a>
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021</a>	<a href="#">F-6</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">F-7</a>

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## Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors  
Aspira Women's Health Inc.  
Woodbridge, New Jersey

### 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, 2022 and 2021, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern Uncertainty

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

### Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

### Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

### 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, 2022 was \$8.0 million.

We identified management's determination of the transaction price as a critical audit matter. Management's determination of the transaction price considers certain inputs, such as payment history, including amount and timing of payment, payer coverage and the existence of reimbursement contracts. Auditing these inputs involved a high degree of subjective auditor judgment.

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

Assessing the reasonableness of management's inputs used to estimate the transaction price by testing on a sample basis (i) the underlying data by payer and ensuring that each item is grouped appropriately based on payer ID, (ii) pertinent underlying information which supports contracted or non-contracted pricing information, (iii) historical cash collection used in determining the transaction price; and recalculating the average unit price over the historical average collection period of each payer class.

#### **Accounting for 2022 Warrant Issuances**

As described in Note 7 to the consolidated financial statements, on August 23, 2022, the Company issued 12 million common stock with warrants to purchase 12 million shares of the Company' common stock. The warrants do not meet the criteria to be classified within equity and are therefore being accounted for as liabilities and recorded at fair value each reporting period.

We identified the assessment of the accounting treatment of the Warrants as equity or liability as a critical audit matter due to the complexity in assessing the warrant features, which requires management to make significant judgments in the interpretation of the terms of the agreements and in the application of appropriate accounting guidance. Auditing management's application of the appropriate accounting treatment required challenging and complex auditor judgment due to the nature and extent of audit effort required, including the extent of specialized skills or knowledge needed.

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

Reviewing and evaluating (i) the terms of the agreements associated with the Warrants, (ii) the completeness and accuracy of the Company's technical accounting analysis, and (iii) the application of the relevant accounting guidance.

Utilizing personnel with specialized knowledge and skills in the relevant technical accounting guidance to assist in: (i) evaluating the relevant contract terms of the warrant issuances in relation to the appropriate accounting guidance, and (ii) assessing the appropriateness of conclusions reached by the Company.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.  
Woodbridge, New Jersey  
March 30, 2023

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

	<b>December 31, 2022</b>	<b>December 31, 2021</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 13,306	\$ 37,180
Accounts receivable, net of allowance of \$9 and \$23, respectively	1,245	1,027
Prepaid expenses and other current assets	1,442	1,624
Inventories	316	174
Total current assets	16,309	40,005
Property and equipment, net	368	464
Right-of-use assets	282	346
Restricted cash	251	250
Other assets	163	14
Total assets	<u>\$ 17,373</u>	<u>\$ 41,079</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 881	\$ 1,501
Accrued liabilities	3,650	5,299
Current portion of long-term debt	403	201
Short-term debt	764	779
Lease liability	77	60
Total current liabilities	5,775	7,840
Non-current liabilities:		
Long-term debt	2,315	2,718
Lease liability	272	349
Warrant liabilities	2,280	-
Total liabilities	10,642	10,907
Commitments and contingencies (Note 2)		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 150,000,000 shares authorized at December 31, 2022 and December 31, 2021; 124,594,888 and 112,138,741 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	125	112
Additional paid-in capital	505,504	501,788
Accumulated deficit	(498,898)	(471,728)
Total stockholders' equity	6,731	30,172
Total liabilities and stockholders' equity	<u>\$ 17,373</u>	<u>\$ 41,079</u>

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)

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenue:		
Product	\$ 7,970	\$ 6,568
Genetics	214	244
Total revenue	<u>8,184</u>	<u>6,812</u>
Cost of revenue <sup>(1)</sup> :		
Product	3,698	3,016
Genetics	167	734
Total cost of revenue	<u>3,865</u>	<u>3,750</u>
Gross profit	4,319	3,062
Operating expenses:		
Research and development <sup>(2)</sup>	5,953	5,314
Sales and marketing <sup>(3)</sup>	14,948	17,086
General and administrative <sup>(4)</sup>	16,183	13,257
Total operating expenses	<u>37,084</u>	<u>35,657</u>
Loss from operations	(32,765)	(32,595)
Change in fair value of warrant liabilities	5,472	-
Interest income (expense), net	17	(48)
Other income, net	106	981
Net loss	<u>\$ (27,170)</u>	<u>\$ (31,662)</u>
Net loss per share - basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.28)</u>
Weighted average common shares used to compute basic and diluted net loss per common share	<u>116,536,631</u>	<u>111,210,614</u>
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:		
(1) Cost of revenue	\$ 80	\$ 161
(2) Research and development	203	311
(3) Sales and marketing	356	1,132
(4) General and administrative	2,037	1,935

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)

	<b>Common Stock</b>		<b>Additional Paid-In Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>			
<b>Balance at December 31, 2020</b>	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
<b>Balance at December 31, 2021</b>	<u>112,138,741</u>	<u>\$ 112</u>	<u>\$ 501,788</u>	<u>\$ (471,728)</u>	<u>\$ 30,172</u>
Net loss	-	-	-	(27,170)	(27,170)
Common stock issued in conjunction with exercise of stock options	23,000	-	13	-	13
Common stock and warrants issued in conjunction with follow-on public offering, net of issuance costs	12,000,000	12	1,028	-	1,040
Common stock issued for restricted stock awards	433,147	1	362	-	363
Stock-based compensation expense	-	-	2,313	-	2,313
<b>Balance at December 31, 2022</b>	<u>124,594,888</u>	<u>\$ 125</u>	<u>\$ 505,504</u>	<u>\$ (498,898)</u>	<u>\$ 6,731</u>

See accompanying notes to consolidated financial statements

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

	<b>Twelve Months Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (27,170)	\$ (31,662)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	4	37
Depreciation and amortization	264	302
Stock-based compensation expense	2,676	3,539
Change in fair value of warrant liabilities	(5,472)	-
Loss on impairment and disposal of property and equipment	64	1
Forgiveness of PPP loan	-	(1,006)
Changes in operating assets and liabilities:		
Accounts receivable	(218)	(162)
Prepaid expenses and other assets	33	(548)
Inventories	(142)	(144)
Accounts payable, accrued liabilities and other liabilities	(2,224)	2,248
Net cash used in operating activities	(32,185)	(27,395)
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(232)	(184)
Net cash used in investing activities	(232)	(184)
<b>Cash flows from financing activities:</b>		
Principal repayment of DECD loan	(261)	(198)
Proceeds from issuance of common stock from exercise of stock options	13	718
Proceeds from public offering	9,000	48,235
Payment of issuance costs for public offering	(208)	(377)
Net cash provided by financing activities	8,544	48,378
Net (decrease) increase in cash, cash equivalents and restricted cash	(23,873)	20,799
Cash, cash equivalents and restricted cash, beginning of period	37,430	16,631
Cash, cash equivalents and restricted cash, end of period	\$ 13,557	\$ 37,430
<b>Reconciliation to Consolidated Balance Sheet:</b>		
Cash and cash equivalents	\$ 13,306	\$ 37,180
Restricted cash	251	250
Unrestricted and restricted cash and cash equivalents	\$ 13,557	\$ 37,430
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	77	77
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Forgiveness of PPP loan	-	(1,006)
Fair value of warrants issued in conjunction with common stock offering	7,752	-

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 (4) OvaWatch, a lab developed blood test intended to assist in the initial clinical assessment of malignancy risk in all women with an adnexal mass. Collectively, these tests are referred to and marketed as OvaSuite. For the year ended December 31, 2022, the Company's product and related revenue was limited to these products, and Aspira GenetiX which was discontinued in the third quarter of 2022. The Company's products are distributed through its own national sales force, through its proprietary decentralized testing platform and cloud service marketed as Aspira Synergy, and through a marketing and distribution agreement with BioReference Health, LLC (formerly known as BioReference Laboratories, Inc.).

***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 \$498.9 million and working capital of \$10.5 million as of December 31, 2022. For the year ended December 31, 2022, the Company incurred a net loss of \$27.2 million and used cash in operations of \$32.2 million. The Company also expects to incur a net loss and negative cash flows from operations for 2023. 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);
- Securing debt, however, no assurance can be given that debt 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.

The Company also has outstanding warrants to purchase shares of its common stock that may be exercised although there can be no assurance that the warrants will be exercised.

There can be no assurance that the Company will achieve or sustain profitability or positive cash flow from operations. Management expects cash from product sales and licensing to be the Company's only material, recurring source of cash in 2023. Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date these financial statements are filed. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

On June 1, 2022, the Company received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that, for the preceding 30 consecutive business days, the closing bid price for Aspira common stock was below the minimum \$1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). On November 29, 2022, the Company was granted an additional 180-calendar day compliance period, or until May 29, 2023, to regain compliance with the minimum bid price requirement. The Company may achieve compliance during this period if the

closing bid price of Aspira common stock is at least \$1.00 per share for a minimum of 10 consecutive business days. There is no assurance that the Company will be able to regain compliance by the May 29, 2023 extended deadline, and there is no assurance that the Company will otherwise maintain compliance with this or any of the other Nasdaq continued listing requirements.

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.

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. 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, warrants, income taxes and contingent liabilities. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

#### ***Cash and Cash Equivalents***

Cash and cash equivalents consist of cash and highly liquid investments with maturities of three months or less from the date of purchase, which are readily convertible into known amounts of cash and are so near to their maturity that they present an insignificant risk of changes in value because of interest rate changes. Highly liquid investments that are considered cash equivalents include money market funds, certificates of deposits, treasury bills and commercial paper.

#### ***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.

Financial instruments of the Company consist primarily of cash and cash equivalents, restricted cash accounts, receivable, and accounts payable, and warrant liability. These items are considered Level 1 due to their short-term nature and their market interest rates, except for warrant liability, which is considered Level 2 and is recorded at fair value at the end of each reporting period.

### ***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 using the first-in-first-out method.

### ***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 – OvaSuite:* 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 OvaSuite 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, 2022 and



2021, 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, 2022 and 2021.

**Genetics Revenue – Aspira GenetiX:** Under ASC 606, the Company’s genetics revenue was recognized upon completion of the Aspira GenetiX test and delivery of results to the physician based on estimates of amounts that would ultimately be realized. In determining the amount of revenue to be recognized for a delivered test result, the Company considered factors such as payment history and amount, payer coverage, whether there was a reimbursement contract between the payer and the Company, and any developments or changes that could impact reimbursement. These estimates required significant judgment by management as the Company has limited experience with such factors relating to Aspira GenetiX.

In September 2022, the Company received a notice of cancellation from its only Aspira Synergy genetics carrier screening customer, Axia Women’s Health. As a result of this cancellation, along with the general deterioration of commercial opportunities in the genetics carrier screening market, has led the Company to cease providing Aspira GenetiX, including genetics carrier screening, on the Aspira Synergy platform, effective as of September 30, 2022. The Company did not incur any termination penalties nor did the Company accrue any expenses as a result of the cancellation. This did not have a material impact on Company revenues in 2022 nor does management expect it to have a material impact in any future periods.

### **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 \$410,000 and \$202,000 for the years ended December 31, 2022 and 2021, 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, warrants 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 warrants is their fair value at the end of the period. 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.

### ***Leases***

The Company determines if a contract, at its inception, is a lease or contains a lease based on whether the contract conveys the right to control the use of identified property, plant, or equipment (an identified asset) for a period of time in exchange for consideration. To determine whether a contract conveys the right to control the use of an identified asset for a period of time, the Company assesses whether, throughout the period of use, it has both the right to obtain substantially all of the economic benefits from use of the identified asset, and the right to direct the use of the identified asset.

Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease the Company (i) identifies lease and non-lease components, (ii) determines the consideration in the contract, (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease ROU assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses an incremental borrowing rate based on the information available at the lease commencement date, which represents a rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include items such as maintenance, utilities, or other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Additionally, the Company has elected the short-term lease exemption and, therefore, do not recognize a ROU asset or corresponding liability for lease arrangements with an original term of 12 months or less.

Operating leases are included in right of use operating assets, current lease liabilities, and noncurrent lease liabilities in the consolidated balance sheet as of December 31, 2022 and 2021.

### **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 ASU requires timelier recording of credit losses on loans and other financial instruments held. Instead of reserves based on a current probability analysis, Topic 326 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. All organizations will now use forward-looking information to better inform their credit loss estimates. Topic 326 requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization's portfolio. These disclosures include qualitative and quantitative requirements that provide information about the amounts recorded in the financial statements. In addition, Topic 326 amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326 Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, to introduce amendments which will affect the recognition and measurement of financial instruments, including derivatives and hedging. In May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments - Credit Losses (Topic 326): Targeted Transition Relief*. The amendments in this ASU provide entities that have certain instruments within the scope of Subtopic 326-20 with an option to irrevocably elect the fair value option in Subtopic 825-10, applied on an instrument-by-instrument basis for eligible instruments upon adoption of Topic 326. This standard and related amendments are effective for the Company's fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The ASU is effective January 1, 2023 for smaller reporting companies, which includes the Company. The adoption of ASU 2016-13 is not expected to have a material impact on the Company's results of operations, financial position, or cash flows.

In March 2020, FASB issued ASU No. 2020-03, *Codification Improvements to Financial Instruments*. This ASU improves and clarifies various financial instruments topics, including the current expected credit losses standard issued in 2016 (ASU No. 2016-13). The ASU includes seven different issues that describe the areas of improvement and the related amendments to GAAP, intended to make the standards easier to understand and apply by eliminating inconsistencies and providing clarifications. The amendments have different effective dates. The issues 1-5 are conforming amendments, which are effective upon issuance of this final update. The Company determined that issues 1-5 have no impact on its financials. The amendments related to issue 6 and 7 effect ASU No. 2016-13, *Financial instruments - credit losses (Topic 326): measurement of credit losses on financial statements*. Effective dates of issue 6 and 7 are the same as the effective date of ASU No. 2016-13. The Company will adopt the new standard in the first quarter of fiscal year 2023. The Company does not expect adoption of this standard will have a material impact on the Company's results of operations, financial position, or cash flows.

In August 2020, the Financial Accounting Standards Board issued Accounting Standard Update No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). This update was issued to assist in simplifying the accounting for convertible instruments. This ASU 2020-06 is scheduled to be effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than

fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is in the process of evaluating the impact of this standard 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 and is billed by Quest Diagnostics for services performed. 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. The parties are continuing to operate under the existing agreement. As of December 31, 2022, the Company has \$296,850 accrued and payable to Quest Diagnostics for phlebotomy services rendered on behalf of the Company under the terms of the agreements.

### NOTE 4: PROPERTY AND EQUIPMENT

The components of property and equipment as of December 31, 2022 and 2021 were as follows:

(in thousands)	December 31,	
	2022	2021
Machinery and equipment	\$ 891	\$ 1,094
Demonstration equipment	-	8
Computer equipment and software	1,386	1,252
Furniture and fixtures	181	174
Leasehold improvements	721	721
Gross property and equipment	3,179	3,249
Accumulated depreciation and amortization	(2,811)	(2,785)
Property and equipment, net	\$ 368	\$ 464

Depreciation expense for property and equipment was \$265,000 and \$302,000 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, property and equipment was reviewed for potential impairment for recoverability by comparing the carrying amount of certain of the Company's assets to the estimated undiscounted future cash flows expected to be generated by the asset group. As the carrying amount of the Company's asset group exceeded its estimated undiscounted future cash flows, the Company recognized an impairment of \$52,000, recorded as selling, general and administrative expense on the consolidated statement of operations, based on the difference between the carrying value of the fixed assets and their fair value as of December 31, 2022 as a result of the Company's discontinuance of the genetics testing offering effective September 30, 2022. The fair value was derived from an offer to purchase certain of the Company's assets for a blanket amount, as the Company's management believes it represents the most appropriate fair value of the asset group.

**NOTE 5: ACCRUED LIABILITIES**

The components of accrued liabilities as of December 31, 2022 and 2021 were as follows:

(in thousands)	December 31,	
	2022	2021
Payroll and benefits related expenses	\$ 2,051	\$ 2,652
Collaboration and research agreements expenses	404	382
Professional services	556	1,992
Other accrued liabilities	639	273
Total accrued liabilities	\$ 3,650	\$ 5,299

**NOTE 6: COMMITMENTS, CONTINGENCIES AND DEBT**

Long-term debt consisted of the following:

(in thousands)	December 31,	
	2022	2021
DECD loan, net of issuance costs	\$ 2,718	\$ 2,919
Less: Current portion, net of issuance costs	(403)	(201)
Total long-term debt, net of issuance costs	\$ 2,315	\$ 2,718

**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 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. The Company was able to achieve the 25 full-time employee milestone. However, the Company has not yet been legally released of the liability and the achievement of the milestone is subject to lender review and approval. If the Company was 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, 2022, 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 \$12,000. Debt related to the insurance promissory note of \$764,000, as described below, is not included in the following table due to the insurance promissory note being cancelable.

(in thousands)	Payments Due by Period						
	Total	2023	2024	2025	2026	2027	Thereafter
DECD Loan	\$ 2,729	\$ 406	\$ 452	\$ 461	\$ 341	\$ 254	\$ 815
Total	\$ 2,729	\$ 406	\$ 452	\$ 461	\$ 341	\$ 254	\$ 815

#### Insurance Notes

During 2022 and 2021, the Company entered into insurance promissory notes for the payment of insurance premiums at an interest rate of 5.48% and 3.74% respectively, with an aggregate principal amount outstanding of approximately \$764,000 and \$779,000 as of December 31, 2022 and 2021, respectively. The amount outstanding in 2022 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, 2023 and October 1, 2022, 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 December 2022, the Company renewed the Austin, Texas lease for one additional year. The Company's renewed lease expires on January 31, 2024, 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. Variable lease costs represent our share of the landlord's operating expenses.

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, 2022 and 2021 is shown in the table below (in thousands). Included in the amounts below are \$114,000 and \$54,000 related to rent and variable costs, respectively, for the Texas lease during 2022 and \$108,000 and \$53,000 related to rent and variable costs, respectively during 2021.

Lease Cost	Classification	Year Ended December 31,	
		2022	2021

Operating rent expense				
	Cost of revenue	\$	79	\$ 59
	Research and development		27	44
	Sales and marketing		37	33
	General and administrative		66	68
Variable rent expense				
	Cost of revenue	\$	39	\$ 32
	Research and development		22	32
	Sales and marketing		34	37
	General and administrative		67	61

Based on the Company's leases as of December 31, 2022, the table below sets forth the approximate future lease payments related to operating leases with initial terms of one year or more (in thousands).

	2023	\$	106
	2024		116
	2025		123
	2026		64
	Total Operating Lease Payments		409
	Less: Imputed Interest		(60)
	Present Value of Lease Liabilities		349
	Less: Operating Lease Liability, current portion		(77)
	Operating Lease Liability, non-current portion	\$	272

Supplemental disclosure of cash flow information related to leases for the years ended December 31, 2022 and 2021 is shown in the table below (in thousands).

	Year Ended December 31,	
	2022	2021
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash outflows relating to operating leases	\$ 371	\$ 366
Weighted-average remaining lease term (in years)	3.5	4.5
Weighted-average discount rate	9.30%	9.33%

#### ***Non-cancelable Royalty 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, 2022 and 2021 totaled \$318,000 and \$263,000, respectively, as recorded in cost of revenue in the consolidated statements of operations.

#### ***Commercial Reorganization***

During the first quarter of 2022, the Company executed a commercial reorganization resulting in the separation of a number of employees. The organizational changes resulted in the recording within the consolidated statement of operations in sales and marketing, research and development and general and administrative expenses of one-time severance, separation, and settlement charges of approximately \$1,284,000. These amounts have been partially offset by insurance reimbursement of \$523,000. All charges have been settled as of December 31, 2022.

#### ***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.

In August 2022, the Company entered into a sponsored research agreement with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz for the generation of a multi-omic, non-invasive diagnostic aid to identify endometriosis based on circulating miRNAs and proteins. The results of this collaboration will be advanced, co-developed technology to guide medical and clinical management of women presenting with symptoms of endometriosis. This collaboration is expected to accelerate the development and commercialization of future endometriosis products, such as EndoCheck. The contract requires payments to be made upon the achievement of certain milestones. Under the terms of and as further described in the agreement, payments of approximately \$1,252,000 have or will become due from the Company to the counterparties upon successful completion of certain deliverables in 2022 and 2023 as follows: 68% was paid in August 2022, 15% will become payable upon completion of certain deliverables estimated to occur in the first quarter of 2023, and 17% will become payable upon completion of certain deliverables estimated to occur in the second quarter of 2023. For the year ended December 31, 2022, the Company made payments totaling \$852,000, all of which were deemed earned by the collaboration partners and are included in research and development expense. Additional payments of \$400,000 are due to the collaboration partners in 2023 under the terms of the agreement.

## **NOTE 7: COMMON STOCK**

### ***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.

### ***2022 Public Offering***

On August 22, 2022, the Company entered into an underwriting agreement (the "2022 Underwriting Agreement") with William Blair & Company, L.L.C., as the sole underwriter (the "2022 Underwriter"). Pursuant to the 2022 Underwriting Agreement, the Company agreed to issue and sell, in an underwritten public offering (the "2022 Offering"), 12,000,000 shares of the Company's common stock, par value \$0.001 per share ("Common Stock") and warrants to purchase up to 12,000,000 shares of Common Stock (the "Warrants"). Each share of Common Stock was sold together with one Warrant to purchase one share of Common Stock, at a price to the public of \$0.75 per share and related Warrant.

The Warrants were issued pursuant to a common stock purchase warrant (the "Form of Warrant"). Each Warrant has an initial exercise price equal to \$0.88 per share of Common Stock and are exercisable for five years from the date of issuance. The exercise price and the number of shares of Common Stock issuable upon exercise of the Warrants are subject to adjustment in the event of certain subdivisions and combinations, including by any stock split or reverse stock split, stock dividend, recapitalization or otherwise. The exercise of the Warrants may be limited in certain circumstances if, after giving effect to such exercise, the holder or any of its affiliates would beneficially own (as determined in accordance with the terms of the Warrants) more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding Common Stock immediately after giving effect to the exercise. There is no established trading market available for the Warrants on any securities exchange or nationally recognized trading system.



The Company accounts for common stock warrants as either equity-classified or liability-classified instruments based on an assessment of the specific terms of the warrants and applicable authoritative guidance in Financial Accounting Standards Board Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815-40, Contracts in Entity's Own Equity ("ASC 815-40"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and meet all of the requirements for equity classification under ASC 815-40, including whether the warrants are indexed to the Company's own stock and whether the events where holders of the warrants could potentially require net cash settlement are within the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. As further described in the Form of Warrant, if the Company consummates any merger, consolidation, sale or other reorganization event, including the sale of all or substantially all of the Company's assets, in which its common stock is converted into or exchanged for securities, cash or other property ("Fundamental Transaction"), then the Company shall pay at the holder's option, exercisable at any time commencing on the occurrence or the consummation of the Fundamental Transaction (or, if later, the date of public announcement) and continuing up to 30 days, an amount of cash equal to the value of the remaining unexercised portion of the Warrant as determined in accordance with the Black-Scholes option pricing model on the date of such Fundamental Transaction provided; however, that if the Fundamental Transaction is not within the Company's control, including not approved by the Board of Directors, the holder of the Warrant shall only be entitled to receive the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the Warrant, that is being offered and paid to the holder of the Common Stock of the Company in connection with the Fundamental Transaction. The Black-Scholes option pricing model, as defined in the Form of Warrant, includes as an input, the highest volume weighted average price ("VWAP") for a period of one trading day preceding the consummation or announcement of a Fundamental Transaction up to 30 days after a Fundamental Transaction. The Company has determined that an adjustment based on this input is not limited to the effect that is attributable to the Fundamental Transaction and therefore causes the Warrants to fail the indexation guidance under ASC 815-40. As a result, the Company has determined that the Warrants must be recorded as derivative liabilities upon issuance and marked to market each reporting period in the Company's consolidated statement of operations until their exercise or expiration.

The fair values of the Warrants as of August 22, 2022, the issuance date, and December 31, 2022 were \$7,752,000 and \$2,280,000, respectively. The fair value of the Warrants was estimated using Black-Scholes pricing model based on the following assumptions:

	December 31, 2022	August 22, 2022
Dividend yield	- %	- %
Volatility	96.8 %	95.0 %
Risk-free interest rate	3.99 %	3.17 %
Expected lives (years)	4.64	5.00
Weighted average fair value	\$ 0.190	\$ 0.646

The fair value of the Warrants was deemed to be derivative instruments due to certain contingent put feature, was determined using the Black-Scholes option pricing model, deemed to be an appropriate model due to the terms of the Warrants issued, including a fixed term and exercise price.

The fair value of Warrants was affected by changes in inputs to the Black-Scholes option pricing model including the Company's stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 2 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At December 31, 2022, the fair value of all Warrants was \$2,280,000, which are classified as a long-term Warrant liability on the Company's balance sheet.

The 2022 Offering resulted in net proceeds to the Company of approximately \$7,675,000, after deducting underwriting discounts and offering expenses of \$1,325,000. Offering costs were allocated between liability expense and equity based on the fair value of the Warrants of \$7,752,000 and the total gross proceeds of \$9,000,000. \$1,117,000 of offering costs were allocated to the Warrants and were expensed immediately and recorded as selling, general and administrative expense in the consolidated statement of operations for the year ended December 31, 2022, resulting in a net impact to the Company's equity of \$208,000.

**Warrants**

Warrants outstanding as of December 31, 2022 and 2021 were as follows:

Issuance Date	Expiration Date	Exercise Price per Share	Number of Shares Outstanding under Warrant	
			December 31, 2022	December 31, 2021
August 25, 2022	August 25, 2027	\$ 0.88	12,000,000	-
			12,000,000	-

**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, 2022 and 2021 was as follows:

(In thousands, except shares and per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
Year ended December 31, 2022:			
Net loss - basic	\$ (27,170)	116,536,631	\$ (0.23)
Dilutive effect of common stock shares issuable upon exercise of stock options	-	-	
Net loss - diluted	<u>\$ (27,170)</u>	<u>116,536,631</u>	<u>\$ (0.23)</u>
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	<u>\$ (31,662)</u>	<u>111,210,614</u>	<u>\$ (0.28)</u>

Due to net losses for the years ended December 31, 2022 and 2021, 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, 2022 and 2021 were as follows:

	Year Ended December 31,	
	2022	2021
Stock options	9,828,424	10,257,908
Warrants	12,000,000	-
Potential common shares	<u>21,828,424</u>	<u>10,257,908</u>

**NOTE 9: EMPLOYEE SHARE BASED COMPENSATION AND 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, 2022, there were no shares of Aspira common stock available for future grants under the 2010 Plan.

As of December 31, 2022, a total of 4,306,561 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, which was later amended to the Aspira Women's Health Inc. (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, 2022, there were 3,576,486 shares of Aspira common stock available for future grants under the 2019 Plan.

As of December 31, 2022, there were 5,521,863 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, 2022 and 2021 was as follows:

	2010 Stock Option Plan	2019 Stock Option Plan	Total
Shares available at December 31, 2020	-	6,504,934	6,504,934
Options forfeited	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 expired	(95,626)	-	(95,626)
Shares available at December 31, 2021	-	3,729,204	3,729,204
Options forfeited	39,750	2,979,315	3,019,065
Options granted	-	(2,612,581)	(2,612,581)
Restricted stock units forfeited	-	5,193	5,193
Restricted stock units granted	-	(438,340)	(438,340)
Shares expired	(39,750)	(86,305)	(126,055)
Shares available at December 31, 2022	-	3,576,486	3,576,486

The stock option activity under the 2010 Plan and the 2019 Plan for the years ended December 31, 2022 and 2021 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
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		
Forfeited	(1,417,272)	4.34		
Options outstanding at December 31, 2021	10,257,908	\$ 2.96	\$ 3,797,181	7.44
Granted	2,612,581	0.91		
Exercised	(23,000)	0.74		
Forfeited	(3,019,065)	2.19		
Options outstanding at December 31, 2022	9,828,424	\$ 1.95	\$ -	6.06
<b>Shares exercisable:</b>				
December 31, 2022	6,320,588	\$ 1.63	\$ -	4.99
<b>Shares expected to vest:</b>				
December 31, 2022	2,649,117	\$ 2.52	\$ -	8.01

The range of exercise prices for options outstanding and exercisable at December 31, 2022 is as follows:

Exercise Price	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Options Exercisable	Weighted Average Exercise Price
\$ 0.38 - \$ 1.01	2,788,619	\$ 0.69	6.45	1,887,119	\$ 0.69
1.04 - 1.28	2,183,060	1.07	7.50	904,060	1.10
1.29 - 2.05	2,563,191	1.53	4.33	2,323,191	1.56
2.08 - 7.79	2,293,554	4.78	6.16	1,206,218	3.65
\$ 0.38 - \$ 7.79	9,828,424	\$ 2.96	7.44	6,320,588	\$ 1.61

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2022	\$ 5	\$ 5,982
Year ended December 31, 2021	\$ 2,903	\$ 4,325

### 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, 2022 and 2021 were as follows:

	December 31, 2022	December 31, 2021
Dividend yield	- %	- %
Volatility	92.7 %	89.0 %
Risk-free interest rate	2.45 %	0.63 %
Expected lives (years)	2.00	3.80
Weighted average fair value	\$ 0.490	\$ 3.940

The allocation of employee and director stock-based compensation expense by functional area for the years ended December 31, 2022 and 2021 was as follows:

(in thousands)	Year Ended December 31,	
	2022	2021
Cost of revenue	\$ 64	\$ 153
Research and development	77	350
Sales and marketing	356	1,210
General and administrative	1,913	1,658
Total	\$ 2,410	\$ 3,371

As of December 31, 2022, total unrecognized compensation cost related to unvested stock option awards was approximately \$4,059,000 and the related weighted average period over which it is expected to be recognized was 2.36 years. As of December 31, 2022, 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, 2022 and 2021, 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, 2022 or 2021 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, 2022 and 2021 were \$27,170,000 and \$31,662,000, 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, 2022 and 2021. Therefore there was no deferred income tax expense or benefit for the years ended December 31, 2022 or 2021.

The components of net deferred tax assets (liabilities) at December 31, 2022 and 2021 were as follows:

(in thousands)	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating losses	\$ 44,227	\$ 38,268
Capitalized research expenses	3,689	2,404
Fixed asset depreciation	678	633
Other	859	587
Total deferred tax assets	49,453	41,892
Valuation allowance	(49,453)	(41,892)
Deferred tax assets	\$ -	\$ -

The Company's gross deferred tax asset for state net operating losses and the valuation allowance for the year ended December 31, 2022 have each been reduced by \$1,259,500 to apply the Internal Revenue Code Section 382 net operating loss utilization limitation to the state of California net operating losses, which was identified by management in the current year and related to the prior period of 2021.

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2022 and 2021 was as follows:

	Year Ended December 31,	
	2022	2021
Tax at federal statutory rate	21 %	21 %
State tax, net of federal benefit	6	(2)
Change in valuation allowance	(28)	(21)
Change in warrant valuation	3	-
Net operating loss and tax credit carryforwards	-	-
Permanent items	(1)	1
Other	(1)	1
Effective income tax rate	- %	- %

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.

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 \$67 million, which are not limited from offsetting future taxable income under Section 382, will expire in varying amounts from 2023 through 2037, if not utilized; and can offset 100% of future taxable income for regular tax purposes. The Company also has pre-2018 federal NOLs that will expire if not utilized within 20 years of being generated that are limited in offsetting future taxable income under Section 382. A portion may still potentially be utilized before they expire, but the portion which will not be able to be utilized prior to expiration has been removed from gross deferred tax assets. The Company's federal NOLs of \$100 million arising after January 1, 2018, can generally be carried forward indefinitely and can offset up to 80% of future taxable income annually. State NOLs will expire in varying amounts from 2023 through 2042 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 valuation allowance was \$49.5 million and \$41.9 million at December 31, 2022 and 2021, respectively. The increase of approximately \$7.6 million between 2021 and 2022 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, 2022, the Company's federal returns for the years ended 2019 through the current period and most state returns for the years ended 2018 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 2019 and 2018, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2021 reflect research and development carryforwards of \$4,937,000 and \$5,644,000, respectively. For the year ended December 31, 2022, the Company anticipates claiming additional research and development credits of \$223,000 on its federal tax return and \$212,000 on its California tax return.

As of December 31, 2022, the Company's gross unrecognized tax benefits are approximately \$10,231,000 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, 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	<u>\$ 4,937</u>	<u>\$ 5,644</u>	<u>\$ 10,581</u>
Return to provision true up	-	-	-
Increase in tax position during 2021	223	212	435
Decrease due to expirations during 2021	(785)	-	(785)
Balance at December 31, 2022	<u>\$ 4,375</u>	<u>\$ 5,856</u>	<u>\$ 10,231</u>

The decrease for the year ended December 31, 2022 relates to the expiration of a portion of the carryforward, which is partially offset by positions taken in the current year. The increase for the year ended December 31, 2021 is related to positions taken in that year, which were substantially offset by the expiration of a portion of the carryforward. If the \$10,231,000 of unrecognized income tax benefit is recognized, approximately \$10,231,000 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, 2022 and 2021. 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

On January 23, 2023, the Company entered into a new sublease agreement for an administrative facility in Palo Alto, California. The Company's sublease term expires on May 31, 2024, with no option for renewal. The fixed lease payment will be approximately \$9,000 per month for the first year and \$10,000 per month for the remainder of the lease.

On February 10, 2023, Aspira Women's Health, Inc. entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement"), with Cantor Fitzgerald & Co., ("Cantor"), as agent, pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of the Company's common stock, par value \$0.001 per share, having an aggregate offering price of up to \$12.5 million, (the "Placement Shares").

Under the Sales Agreement, Cantor may sell the Placement Shares by any method permitted by law and deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Company's common stock or

to or through a market maker or in privately negotiated transactions. From time to time, the Company may instruct Cantor not to sell the Placement Shares if the sales cannot be effected at or above the price designated by us.

The Company is not obligated to make any sales of the Placement Shares under the Sales Agreement. The offering of the Placement Shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the Placement Shares subject to the Sales Agreement or (b) the termination of the Sales Agreement by Cantor or us, as permitted therein.

The Sales Agreement contains customary representations, warranties and agreements by us, and customary indemnification and contribution rights and obligations of the parties. The Company will pay Cantor a commission rate of 3.0% of the aggregate gross proceeds from each sale of Placement Shares. The Company will also reimburse Cantor for certain specified expenses in connection with entering into the Sales Agreement.

On March 28, 2023, we entered into an agreement, (the “LPC Agreement”) with Lincoln Park Capital Fund LLC (“Lincoln Park”), pursuant to which we have the right to sell to Lincoln Park shares of our common stock, having an aggregate value of up to \$10 million, subject to certain limitations and conditions, at our sole discretion during a 36-month period ending March 27, 2026. In connection with the LPC Agreement, we issued 715,990 shares of our common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock. We did not receive any cash proceeds from the issuance of these commitment shares. .



## 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 30, 2023

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

Date: March 30, 2023

/s/ Marlene McLennan  
Marlene McLennan  
Interim 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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Nicole Sandford</u> Nicole Sandford	President and Chief Executive Officer (Principal Executive Officer) and Director	March 30, 2023
<u>/s/ Marlene McLennan</u> Marlene McLennan	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2023
<u>/s/ Veronica G. H. Jordan</u> Veronica G. H. Jordan	Chair of the Board of Directors	March 30, 2023
<u>/s/ Robert Auerbach</u> Robert Auerbach	Director	March 30, 2023
<u>/s/ Celeste Fralick</u> Celeste Fralick	Director	March 30, 2023
<u>/s/ Ruby Sharma</u> Ruby Sharma	Director	March 30, 2023