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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023 or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number: 001-34810

Aspira Women's Health Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0595156**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
12117 Bee Caves Road, Building III, Suite 100	
Austin, Texas	**78738**
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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 ☒

The aggregate market value of voting common stock held by non-affiliates of the registrant is $17,677,058 and is based upon the last sales price as quoted on The Nasdaq Capital Market as of June 30, 2023.

As of March 28, 2024, the registrant had 12,344,104 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 2024 Annual Meeting of Stockholders is incorporated by reference into Part III of this report.

ASPIRA WOMEN'S HEALTH INC.

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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 the was 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;
- ability to maintain 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, adenomyosis fibroids and benign pelvic mass monitoring;
- our planned business strategy and the anticipated effects thereof, including partnerships such as those based on our Aspira Synergy platform, specimen or research collaborations, licensing arrangements and distribution agreements;
- plans to expand our current or future products to markets outside of the United States;
- plans to develop new algorithms, molecular diagnostic tests, products and tools and otherwise expand our product offerings;
- plans to develop, launch and establish payer coverage and secure contracts for current and new products, including EndoCheck, EndoMDx and OvaMDx;
- expectations regarding local and/or national coverage under Novitas, our Medicare Administrative Carrier;
- anticipated efficacy of our products, product development activities and product innovations, including our ability to improve sensitivity and specificity over traditional diagnostics;
- expected competition in the markets in which we operate;
- plans with respect to Aspira Labs, Inc. ("Aspira Labs"), including plans to expand or consolidate Aspira Labs' testing capabilities, specifically, molecular lab 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 as laboratory developed tests ("LDTs") and potential Food and Drug Administration ("FDA") oversight changes of LDTs;
- expectations regarding existing and future collaborations and partnerships for our products, including plans to enter into decentralized arrangements for our Aspira Synergy platform and to provide and expand access to our risk assessment tests;
- plans regarding future publications and presentations;
- 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 current and prospective diagnostic tests, including Ova1, Overa, Ova1Plus, EndoCheck, EndoMDx and OvaMDx, as well as our Aspira Synergy platform;
- expectations regarding our ability to launch new products we develop or license, co-market or acquire;
- expectations regarding the size of the markets for our products;
- expectations regarding reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans;
- potential plans to pursue clearance designation with the FDA with respect to EndoCheck and OvaWatch;
- expected potential target launch timing for future products;
- 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;
- ability to protect and safeguard against cybersecurity risks and breaches;
- plans to use samples received from the University of Oxford in verifying and validating our endometriosis blood test algorithms; 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; 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; our 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 or force majeure or acts of God; 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

Aspira Women's Health Inc. is dedicated to the discovery, development, and commercialization of noninvasive, AI-powered tests to aid in the diagnosis of gynecologic diseases.

Our commercially available portfolio includes OvaWatch and the Ova1Plus workflow, offered to clinicians as OvaSuite. Together, they provide the only comprehensive portfolio of blood tests to aid in the detection of ovarian cancer for the more than 1.2 million women in the United States diagnosed with an adnexal mass each year. OvaWatch is used to assess ovarian cancer risk for women with an adnexal mass where their initial clinical assessment indicates the mass is indeterminate or benign. With a negative predictive value of 99%, OvaWatch can help physicians determine the appropriate care pathway. The Ova1Plus workflow is designed to assess the risk of ovarian malignancy in women planned for surgery and uses two FDA-cleared tests, Ova1 as the primary test and Overa as a reflex for Ova1 intermediate range results.

Our focus remains on three key initiatives: growth, innovation, and operational excellence:

Growth. As a revenue-generating diagnostics company focused exclusively on gynecologic disease, our commercial capabilities are one of our most important differentiators. We expect our extensive experience with gynecologists and healthcare providers, along with the historical adoption of our OvaSuite tests, to drive growth as we introduce new products.

Improving our commercial capabilities was one of our most important strategic priorities in 2023. At the beginning of the year, we conducted a comprehensive review of our commercial programs to identify people, processes, and technology enhancements. As a result of the findings of that review, we launched a strategic commercial refresh (the "Commercial Refresh") in the second half of the year. Enhancements focused on improving the profitability, efficiency, and effectiveness of the sales and marketing teams. This year we:

- Recruited a new leadership team with proven success in driving growth in women's health diagnostics;
- Created a Vice President role focused on strategic providers and commercial partnerships;
- Eliminated unprofitable territories;
- Replaced underperforming field sales representatives;
- Established a remote sales team to support field sales and grow "white space" in the market;
- In-sourced marketing with experienced healthcare marketing professionals;
- Expanded our direct-to-physician communications via sales enablement, digital tools and campaigns;
- Implemented a new social media strategy;
- Refreshed all market-facing materials;
- Enhanced CRM processes and accountabilities;
- Expanded sales analytics capabilities;
- Hired internal market access and reimbursement team with women's health diagnostic experience;
- Created a Clinical Advisory Board.

Our earnings quality was positively impacted throughout the year because of these enhancements. The OvaSuite portfolio demonstrated strong year-over-year growth, increasing 11.9% in volume and 14.8% in revenue in 2023 when compared with 2022, while total sales and marketing expenses decreased 48% over the same time period. The single-use OvaWatch test, which was introduced at the end of 2022, saw volume growth as physicians recognized its ability to fill an unmet need in the management of adnexal masses. In addition, we reduced the number of full-time representatives from 24 representatives on January 1, 2023, to 17 representatives on December 31, 2023, the latter of which included 2 lower cost remote salespeople, helping to drive a 50% increase in the average OvaSuite volume per full-time sales representative, from 779 tests per representative in 2022 to 1,170 tests per representative in 2023.

We plan to complete the Commercial Refresh in 2024 prior to the anticipated introduction of new products. We expect to add an additional 6 full-time employees to the commercial organization, including strategic account leaders for the east and west regions of the United States.

Innovation. We believe our ability to successfully develop novel AI-enabled assays is superior to others based on our know-how and extensive experience in designing and successfully launching FDA-approved and laboratory developed

blood tests to aid in the diagnosis of ovarian cancer. We own and operate Aspira Labs, Inc., a research and commercial CLIA laboratory in Texas, has accumulated more than 110,000 patient samples in our research biobank. Moreover, our history of successfully collaborating with world-class research and academic institutions allows us to innovate and provide outstanding patient care.

Our product pipeline is focused on two areas: ovarian cancer and endometriosis.

In ovarian cancer, we have developed clinical data to support the use of our OvaWatch test multiple times for the monitoring of an adnexal mass. We also made significant progress in the development of OvaMDx, a multi-marker test that combines serum proteins, clinical data (metadata) and miRNA for assessing the risk of ovarian cancer in women with an adnexal mass. The test is being developed in collaboration with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz.

In endometriosis, we are developing and intend to introduce a new noninvasive test to aid in the diagnosis of this debilitating disease that impacts millions of women worldwide. We completed the design of EndoCheck, a protein-based blood test to aid the detection of endometrioma, one of the most common forms of endometriosis. EndoCheck is the first ever noninvasive test of its kind, a significant achievement. The algorithm was confirmed with three independent cohorts and is an important input for our EndoMDx test, a multi-marker test that combines serum proteins, clinical data (metadata) and miRNA for the identification of endometriosis which is also in development.

We estimate that the addressable market for products in our pipeline is significant. Expanding the use of OvaWatch as a longitudinal monitoring test has the potential to benefit the more than 1.2 million women in the United States diagnosed each year with an adnexal mass.

Our endometriosis portfolio addresses an even larger addressable market. According to the U.S. Department of Health and Human Services, endometriosis affects more than 6.5 million women in the United States. We believe the proliferation of commercially available and in-development therapeutics for the treatment of endometriosis will create a significant demand for a non-invasive diagnostic.

Operational Excellence. During 2023, we decreased our operating expenses by $11.3 million, while increasing our gross profit per unit by $20.72 per test.

Additionally, we achieved our cash utilization goals for 2023 by focusing on spending that fuels innovation and growth. We have achieved significant reductions in cash used in operations during 2023, while simultaneously increasing sales and accelerating product development. We raised gross proceeds of $4.7 million in July 2023 in a follow-on equity offering, as well as additional gross proceeds of $5.5 million in January 2024 in a separate follow-on offering. We intend to utilize existing facilities and non-dilutive sources of liquidity to provide the resources needed to execute our strategic priorities.

During 2023, unprofitable sales territories were reviewed for remediation or elimination, resulting in consolidations that continued a trend that started in the spring of 2022.

Scientific Basis 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). Protein biomarkers (our entrenched technology), miRNA molecular biomarkers and metadata (age, body mass index, etc.) each provide independent and non-overlapping evidence for a disease state. This increases the accuracy, sensitivity and specificity of the test in most cases.

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 commercialize the following products and related services: (1) the Ova1Plus workflow, which uses Ova1, a qualitative serum 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, as the primary test and Overa, a second-generation biomarker test intended to maintain Ova1's high sensitivity while improving specificity, as a reflex for Ova1 intermediate range results, leveraging the strengths of Ova1's MIA sensitivity and Overa's (MIA2G) specificity to reduce incorrectly elevated results; and (2) OvaWatch, an LDT intended to assist in the initial clinical assessment of malignancy risk in all women thought to have an indeterminate or benign adnexal mass. Overa is currently not offered except as a reflex test performed as part of the Ova1Plus workflow. 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 marketing and distribution agreements, such as BioReference Health, LLC, a subsidiary of OPKO Health, Inc. ("BRL") and ARUP Laboratories.

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 Ova1 and OvaWatch is included in the results of operations in total revenue for the year ended December 31, 2023.

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 the Ova1Plus workflow continue to be available through the Aspira Synergy platform. As of December 31, 2023, we had one active Aspira Synergy contract.

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 has 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 longitudinal testing. The launch of the longitudinal monitoring test is targeted for the second quarter of 2024. We believe OvaWatch has the potential to significantly expand the addressable market compared to the Ova1Plus workflow.

Outside of the United States, we have sponsored studies in both the Philippines and Israel, which were intended to validate Overa and Ova1 in specific populations. In February 2024, we signed a distribution agreement with Hi-Precision Laboratories in the Philippines.

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 Ova1Plus workflow and OvaWatch testing, 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 Administrative Carrier, covers and reimburses for Ova1 tests performed in certain states, including Texas. Due to our billed Ova1 tests being performed exclusively at Aspira Labs in Texas, the Local Coverage Determination ("LCD") from Novitas Solutions provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. We have applied for an LCD for OvaWatch, which is currently under review.

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 an ACOG 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.

- **OvaWatch** is the only commercially available blood test to assess the risk of ovarian cancer in women diagnosed with an adnexal mass considered indeterminate or benign by initial clinical assessment. In January 2023, we published a manuscript entitled: "*Validation of deep neural network-based algorithm supporting the clinical management of adnexal mass*," in Frontiers in Medicine, a peer-reviewed journal to support the clinical adoption of OvaWatch as a single-use test. We have collected additional clinical data to support the use of OvaWatch as a longitudinal monitoring test and have submitted two manuscripts for peer review publication. Abstracts related to both manuscripts were published in the 2023 Journal of Clinical Oncology's Supplement to the American Society of Clinical Oncology's 2023 Annual Conference.

- **OvaMDx** is a multi-marker test that combines serum proteins, clinical data (metadata) and miRNA for assessing the risk of ovarian cancer in women with an adnexal mass. The test is being developed in collaboration with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz. We are currently in the process of completing final test design, including conducting verification experiments to transfer the test to the FDA approved PCR system, which is expected to be completed by mid-2024.

  The miRNAs used in the OvaMDx test were the subject of a 2017 paper, "*Diagnostic potential for a serum miRNA neural network for detection of ovarian cancer*" published in the peer-reviewed journal Cancer Biology. In October 2023, a poster entitled "*Improving the diagnostic accuracy of an ovarian cancer triage test using a joint miRNA-protein model*," was presented at the AACR Special Conference in Cancer Research: Ovarian Cancer by senior author, Dr. Kevin Elias M.D., Director, Gynecologic Oncology Laboratory at Brigham and Women's Hospital and Assistant Professor of Obstetrics, Gynecology and Reproductive Biology at Harvard Medical School. The poster highlighted data from a study that combined serum protein and patient clinical information (metadata) from Aspira's ovarian cancer registry studies with miRNA determined by the Elias laboratory. The data showed using miRNA in combination with metadata provides superior performance over existing ovarian cancer risk assessment blood tests.

  In December 2023, we began the process of completing the final test design, and currently are conducting verification experiments to transfer the test from the current system to an FDA approved PCR system. We expect to complete final test design by the first half of 2024, with final verification and validation of the assay to be completed before the end of 2024.

- **EndoCheck** is the first protein biomarker test designed to identify ovarian endometriomas, one of the most common forms of endometriosis. We have confirmed the algorithm with three independent cohorts, achieving preliminary performance that supports its use to aid the detection and treatment of endometrioma. Data related to the performance of EndoCheck was presented at the 71st Annual Scientific Meeting for the Society for Reproductive Investigation (SRI) in Vancouver, Canada in March 2024. We are currently evaluating the potential commercial application and appropriate launch timeline for EndoCheck.

- **EndoMDx** is a multi-marker test that combines serum proteins, clinical data (metadata) and miRNA for the identification of endometriosis. The test is being developed in collaboration with a consortium of academic and clinical partners led by Dana Farber Cancer Institute. We are currently in the process of completing final test design, including conducting verification experiments to transfer the test to an FDA approved PCR system, which is expected to be completed by mid-2024.

Studies and Publications

In January 2023, a manuscript, "Validation of Deep Neural Network-based Algorithm Supporting Clinical Management of Adnexal Mass," was published in the peer-reviewed journal, Frontiers in Medicine. The paper presents findings from the multi-site clinical study of our newest assay, OvaWatch, describing real-world evidence supporting the use of OvaWatch for the clinical management of adnexal masses.

For the 2023 American Society of Clinical Oncology (ASCO) Meeting, which took place in June 2023, we published three abstracts online: (1) *Multivariate index assay (MIA3G) to reduce preventive surgery for ovarian cancer*, (2) *Serial monitoring of ovarian cancer risk in women with adnexal mass,* and (3) *Multivariate index assay MIA3G vs other assessment tools for the ovarian cancer risk assessment of indeterminate masses*.

In 2024, we submitted two manuscripts for peer review publication based on these abstracts.

We have 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 longitudinal testing using the OvaWatch longitudinal mass monitoring test, in 2022 we launched a study to support the validation of our 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 have also supported ex-U.S. studies in both 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 2023, Fortune Business Insight, a market research and business consulting partnership, published a study which forecasts the global *in vitro diagnostic* ("IVD") market to reach $157.02 billion by 2030, growing at a compound annual growth rate of 7.1% from 2023 to 2030. We have chosen to concentrate our business focus in the areas of gynecologic oncology and disease 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 will increase and the demand for quality diagnostic, prognostic and predictive tests will escalate. In addition, the areas of gynecologic oncology and disease 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 2023, 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 ACS, 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. Studies have indicated that the prevalence of simple ovarian cysts in women 55 years of age and older can be as high as 14%. Adnexal masses are thought to be even more common in premenopausal women. For instance, a University of Kentucky ovarian cancer screening study found that the rate of postmenopausal women with persistently abnormal ultrasound findings requiring surgery was 1.4%. According to 2020 U.S. census data, there are 42.6 million women between the ages of 50 and 70 in the U.S., suggesting that there are nearly 600,000 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 the Ova1Plus workflow. 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, studies have shown that 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. 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 indicate that transvaginal ultrasounds are rarely conclusive 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.

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."

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.

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. In 2022, another study was released indicating superior clinical performance of Ova1 over CA125 in Filipino women.

Commercialization and Distribution

We market and distribute our 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 BRL, as a new channel for volume growth. Under terms of the agreement, the Aspira and BRL sales teams 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. In 2022, the agreement was amended to include OvaWatch testing services.

Customers

In the United States, our clinical customer base includes 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 either bill third party payers or bill clients through 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 our 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 Aspira Labs, a CLIA certified clinical laboratory in Austin, Texas. 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 23,900 OvaSuite tests were performed in 2023 compared to 21,423 in 2022. In 2023, we continued to increase sales through our commercial team, including field sales, strategic alliance and inside sales representatives. 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 by driving physician demand. They work 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 OvaSuite.

We successfully launched a comarketing arrangement for the Ova1Plus workflow with BRL on October 5, 2022. Under terms of the agreement, the Aspira and BRL sales teams 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. 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 more than three 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 longitudinal monitoring test that was launched in the fourth quarter of 2022 could 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, our Medicare Administrative Contractor, covers and reimburses for Ova1 tests performed based on an LCD in its jurisdiction. Due to Ova1 tests being performed at Aspira Labs in Texas, an LCD from Novitas Solutions 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, 2023, Aspira's product and related services revenue was primarily limited to revenue generated by sales of Ova1, Aspira GenetiX (discontinued in September 2022) and OvaWatch (launched in December 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 Laboratory Fee Schedule ("CLFS"), effective January 1, 2018. Under the new fee schedule, the price for Ova1(CPT 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 2024. In 2023 CMS announced that it would continue to delay the period during which rates would be evaluated for another year. Therefore, we will not be responsible for providing reimbursement rates until 2025. There are no assurances that reimbursement rates will not be changed.

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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. Legislation to expand access to multi-cancer early detection technology under Medicare was reintroduced in the current legislative session. HR 2407, introduced in March 2023, and S 1085, introduced in June 2023, would create the authority for CMS to cover blood-based multi-cancer early detection tests once approved by FDA and shown to have clinical benefit.

We have a comprehensive reimbursement plan for Ova1 and OvaWatch, and have targeted third-party payers, Medicare, Medicare Advantage, State Medicaid and Managed Medicaid plans for coverage and reimbursement. In April 2023 we began billing OvaWatch with our newly awarded Proprietary Laboratory Analyses ("PLA Code") 0375U. Since we began billing OvaWatch with the PLA Code, our reimbursement has been more in-line with historical Ova1Plus experience, resulting in the OvaWatch average unit price ("AUP") of $339 in the fourth quarter of 2023.

Ova1 is considered medically necessary in the Lab Management Guidelines for one of the largest lab benefit management companies who works with payers to ensure adherence to clinical guidelines. We continue to make gains toward reimbursement for OvaWatch as we build clinical evidence to support coverage.

In February 2023, we signed a contract with a national commercial payer which provides patient coverage for Ova1 and OvaWatch beginning in April 2023. Further, CMS approved the crosswalk of the fee to be paid for OvaWatch to the fee paid for Ova1. Effective January 1, 2024, we will be reimbursed at a rate of $897 for all OvaWatch and Ova1 tests processed for Medicare patients meeting applicable coverage requirements.

In addition, the United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

Further, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal

year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional congressional action is taken.

The Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act and the Medicare Multi-Cancer Early Detection Screening Coverage Act are bills that modernize the Medicare program and create a benefit category for MCED tests, which allow the Centers for Medicare and Medicaid Services (CMS) to initiate an evidenced-based coverage process for multi-cancer tests upon approval by the Food and Drug Administration (FDA). The House bill (H.R. 2407) was introduced with bipartisan support on March 30, 2023 and its Senate companion (S. 2085) was introduced on June 22, 2023.

There may be additional health reform initiatives by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payers.

Biomarker legislation continues to gain momentum on the state level with many states enacting legislation requiring coverage in both public and private insurance plans. Additionally, more states are evaluating legislation and introduced biomarker access bills in 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 sensitivity when compared to the Fujirebio Diagnostics test.

In addition, competitors such as Abbott Laboratories, Angle plc, Anixa Biosciences, Inc., AOA Dx, Becton Dickinson & Co., ClearNote Health, Exact Sciences Corp., Grail and InterVenn Biosciences 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 endometriosis offerings. Competitors include, but are not limited to, DotLab, Endodiag, HERA Biotech and Ziwig. 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.

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 the Form 10-K, our clinical diagnostics patent portfolio included 19 issued United States patents, 8 pending United States patent applications and numerous pending patent applications and issued patents outside the United States. These patents and patent applications are directed to diagnostic technologies.

Manufacturing

We are the manufacturer of FDA cleared products Ova1 and Overa, which are part of the Ova1Plus workflow. We also perform OvaWatch as an LDT. 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 for the component reagents 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 make take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

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

Pre-Market Authorization and Notification

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 a 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.

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.

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* or other 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, data from at least one clinical trial is required to support a PMA application. Evidence from clinical studies also typically is included in a request for *de novo* classification and, less frequently, in 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. Some studies of IVDs are entirely exempt from the IDE requirements. 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 IVD products with the FDA and to comply with the applicable provisions of 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 to support FDA marketing authorization of new IVD products or new indications for already-authorized IVD products must be conducted in accordance with the applicable FDA regulations.

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."

Our clinical laboratory activities are subject to CLIA and related state clinical laboratory 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, Maryland, New York, Pennsylvania, and Rhode Island. 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.

Laboratory Developed Tests

The FDA considers LDTs to be tests that are designed, developed, validated and used within a single laboratory. LDTs are performed using a variety of laboratory instruments and reagents and may also incorporate FDA-authorized IVDs that the laboratory modifies in some way and validates for its new use. 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.

In September 2023, the FDA announced a proposed regulation that would, if adopted, alter the FDA's historical exercise of enforcement discretion for LDTs by classifying LDTs as medical devices. The proposed regulation would subject LDTs to a more stringent regulatory framework, including premarket clearance or approval requirements, quality system regulations, and post-market surveillance obligations. Failure to comply with these and other FDA regulations could result in legal actions, including fines and penalties. The FDA has indicated it plans to finalize the proposed rule in the second quarter of 2024, though it is uncertain whether the FDA will finalize the proposed rule on this timeline or at all.

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 and again in March 2023; the prospects for enactment are uncertain. 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.

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, 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.

Privacy and Security of Health Information

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and final omnibus rules, were issued by HHS to protect the privacy and security of protected health information used or disclosed by health care providers, such as us. HIPAA also

regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties. In addition to federal privacy regulations, a number of state and international laws govern confidentiality of health information.

Health Care Fraud and Abuse

The federal Anti-Kickback Statute makes it a felony for a provider or supplier, including a laboratory, to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal health care program, including Medicare and Medicaid. A violation of the federal Anti-Kickback Statute may result in imprisonment for up to five years and/or criminal fines of up to $250,000 for an individual. Companies may be criminally fined up to $500,000 and may also be subject to civil assessments and exclusion from participation in Medicare, Medicaid, and other federal health care programs.

Actions that violate the federal Anti-Kickback Statute may also be subject to liability under the Federal False Claims Act, which prohibits knowingly presenting or causing to be presented a false or fraudulent claim for payment to the U.S. Government. Although the federal Anti-Kickback Statute applies only to federal health care programs, a number of states have enacted statutes substantially similar to the federal Anti-Kickback Statute pursuant to which similar types of prohibitions are made applicable to all other health plans and third-party payors.

The Eliminating Kickbacks in Recovery Act (EKRA) makes it a federal crime to knowingly and willfully solicit or receive any remuneration, directly or indirectly, in return for referring a patient or patronage any laboratory. EKRA also prohibits paying or offering any remuneration directly or indirectly: (A) to induce a referral of an individual to a laboratory; or (B) in exchange for an individual using the services of a laboratory. Although EKRA's language is similar to the language of the federal Anti-Kickback Statute, EKRA is broader than the AKS in that it applies to all health care benefit programs, including private payors, while the AKS applies only to items and services paid for by federal health care programs.

Federal and state law enforcement authorities scrutinize arrangements between laboratories and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals. The law enforcement authorities and the courts have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between health care providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the federal Anti-Kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals, even if the arrangement has other, legitimate purposes.

In December 1994, the HHS Office of Inspector General, or OIG, issued a Special Fraud Alert on arrangements for the provision of clinical laboratory services. The Fraud Alert set forth a number of practices allegedly engaged in by some clinical laboratories and health care providers that raise issues under the federal fraud and abuse laws, including the federal Anti-Kickback Statute. The OIG emphasized in the Special Fraud Alert that when one purpose of such arrangements is to induce referrals of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider (e.g., physician) may be liable under the federal Anti-Kickback Statute and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Recognizing that the federal Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, Congress authorized, and HHS has issued, a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions which, if all of their requirements are met, will assure health care providers and other parties that they may not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. A non-safe harbored arrangement is evaluated by government enforcement agencies on a case-by-case basis.

In addition, the federal False Claims Act prohibits a person from knowingly submitting or causing to be submitted a false claim or making a false record or statement material to a false claim in order to secure payment by the federal government. Violation of the federal False Claims Act may result in fines of up to three times the actual damages sustained by the government, plus mandatory civil penalties of up to $27,894 for each separate false claim.

Moreover, a federal law directed at "self-referrals," commonly known as the Stark Law, prohibits, with certain exceptions, laboratories from presenting or causing to be presented claims to Medicare and Medicaid for laboratory tests referred

by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the clinical laboratory performing the tests. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid program in violation of the Stark Law is subject to civil monetary penalties of up to $15,000 per claim submission, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal health care programs. Claims submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited claim is obligated to refund such amounts. Many states, including California, also have “anti-self-referral” and other laws that are not limited to Medicare and Medicaid referrals.

Further, in addition to the privacy and security regulations described above, HIPAA created two federal crimes: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including both government and private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

Finally, federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Entities found in violation may be liable for civil monetary penalties of up to $20,000 for each wrongful act.

Other Business Updates

On October 13, 2023, the Audit Committee of the Board and our management determined that our previously issued financial statements in its Annual Report on Form 10-K for the year ended December 31, 2022, as well as the previously filed Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, should be restated and should no longer be relied upon due to an error in the accounting for certain warrants issued in August 2022 as part of our underwritten offering with William Blair & Company, LLC. We restated our financial statements for the year ended December 31, 2022, and the unaudited interim financial statements for the three and nine months ended September 30, 2022 to reflect the correction of the error on October 26, 2023.

Employees

As of December 31, 2023, we had 64 full-time employees. We generally engage independent contractors on a part-time basis from time to time.

Corporate Information

We were originally incorporated in 1993, and we had our initial public offering in 2000. Our executive offices are located at 12117 Bee Caves Road, Building III, Suite 100, Austin, Texas 78738, and our telephone number is (512) 519-0400. We maintain a website at www.aspirawh.com where general information about us is available.

Information About Us

We file annual reports, quarterly reports, current reports, proxy statements, and other information with the SEC.

The SEC maintains an Internet website, www.sec.gov, that contains reports, proxy statements, and other information regarding issuers that file electronically with the SEC.

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 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 2024. 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 2023 and in 2022 was 23,990 and 21,423, respectively. If we are unable to substantially 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 $518.3 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 2024 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.

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. 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, 2023, we had 10,645,049 shares of our common stock outstanding and 165,861 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 759,922 shares of our common stock that were subject to outstanding options and 59,463 restricted stock units. In addition, as of December 31, 2023, warrants to purchase 799,985 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 $13.20 per share.

On January 26, 2024, we closed a follow-on equity offering. In conjunction with the offering, certain of outstanding warrants to purchase up to an aggregate of 366,664 shares at an exercise price of $13.20 per share and a termination date of August 25, 2027, were amended so that the amended warrants have a reduced exercise price of $4.13 per share and a new termination date of January 26, 2029. The other terms of the amended warrants remain unchanged.

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

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.

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.

The great majority of laboratory tests in the United States are paid for by third party payers. Accordingly, our current revenues are from, 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 our products and for which indications. Some payers have determined not to cover our tests. While Novitas Solutions, the Medicare Administrative Contractor responsible for paying Medicare claims for all Aspira laboratory tests, has determined to cover Ova1, there is no assurance that they will continue to do so. Moreover, while The Centers for Medicare & Medicaid Services ("CMS") has issued PAMA reimbursement rates for Ova1 effective January 1, 2018, there is no guarantee that the payment rates will not be reduced. Although the PAMA legislation allows for no more than a 15% fee reduction between 2023 and 2024, uncertainty regarding reimbursement rates could create payment uncertainty from other payers as well. The reimbursement rates for Ova1 and OvaWatch are reviewed by third-party payers. We have experienced volatility in the coverage and reimbursement of our products 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 could be 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"), who create policy and implement utilization management strategies for their payer clients to ensure tests are medically necessary. In addition, more payers are implementing pre-authorization requirements for our testing. These measures have resulted in reduced payment rates and decreased utilization of our tests. 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. Even if favorable coverage and reimbursement status is attained for one or more products by governmental and commercial third-party payers, less favorable coverage policies and reimbursement rates may be implemented in the future. Reductions in third-party payer reimbursement rates may occur in the future. Reductions in the price at which our products are 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 adequate 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.

Failure to continue coverage of Ova1 through Novitas, our Medicare Administrative Contractor 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 (the "Biomarkers for Oncology LCD") issued by Novitas, the Medicare Administrative Contractor responsible for payment of Medicare claims for all Aspira Labs tests. In June 2023, in conjunction with the publication of a final "Genetic Testing for Oncology" LCD (the "Genetic Testing LCD"), Novitas announced that it intended to retire the Biomarkers for Oncology LCD effective July 17, 2023, and that at that time, non-genetic tests currently identified as covered in that LCDs (like Ova1) would be considered for payment based on Medicare medically reasonable and necessary threshold for coverage.

On July 6, 2023, Novitas issued a statement announcing that the Genetic Testing LCD would not go into effect on July 17, 2023 as planned, and that a new proposed LCD would be published for public comment. Novitas issued a replacement proposed LCD for public comment on July 27, 2023. The Biomarkers for Oncology LCD remains in effect.

All OvaSuite tests (Ova1, Overa, Ova1Plus and OvaWatch) are protein-based multivariate index assays and were not impacted by the now-withdrawn Genetic Testing LCD. While we do not believe Novitas intends to eliminate Ova1 coverage, it is impossible to assess the likelihood or potential impact, if any, of future actions to be taken by Novitas with respect to the release of a replacement Genetics Testing LCD, or a change to the content or status of the Biomarkers for Oncology LCD, 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 our products could materially and adversely affect our business, financial condition and results of operations.

We have implemented strategies to expand payer coverage for our ovarian cancer risk assessments, including securing coverage for OvaWatch that is consistent with existing coverage for Ova1. In November 2023, CMS approved our request to provide reimbursement for OvaWatch that is consistent with the reimbursement for Ova1 at $897 per test. However, there can be no assurances that we will be able to secure additional payer coverage for Ova1 and comparable coverage for OvaWatch, or that that the reimbursement rate for OvaWatch will not be reduced. Failure to expand payer coverage and maintain adequate reimbursement rates may have a significant negative impact on product adoption and our results of operations.

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, our ability to obtain sufficient samples to complete the design and development of our algorithms 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 our risk assessment screens for endometriosis 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. In addition, our efforts to develop other diagnostic tests, such as EndoMDx and OvaMDx, are in the early development phase, and future pre-clinical or clinical studies may not support our early data. While the discovery phase has been completed for EndoCheck, it is still pending pre-clinical or clinical studies to support 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 the Ova1Plus workflow with BRL. Under terms of the agreement, the Aspira and BRL sales teams 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 or to change their ordering habits, 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 the Ova1Plus workflow that has adversely impacted and may continue to materially adversely impact our revenue. In addition, competitors, Abbott Laboratories, Angle plc, Anixa Biosciences, Inc., AOA Dx, Becton Dickinson & Co., ClearNote Health, Exact Sciences Corp., Grail, InterVenn Biosciences 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.

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. Competitors for our endometriosis offerings include, but are not limited to, DotLab, Endodiag, HERA Biotech and Ziwig. 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 our 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.

We are currently offering and developing multiple tests as LDTs and intend to develop and perform LDTs at Aspira Labs in the future. Should FDA disagree that our tests are LDTs or finalize regulations that require PMA approval or 510(k)clearance of such tests, their commercialization would be adversely affected, which would negatively affect our results of operations and financial condition.

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. On October 3, 2023 proposed FDA regulations were published in the Federal Register that would phase out the FDA's enforcement discretion approach to LDTs over a period of four years. The proposed regulation would classify all LDTs as medical devices, which would require us to adhere to a more stringent regulatory framework, including premarket clearance or approval requirements, quality system regulations, and post-market surveillance obligations. If the proposed regulation is finalized, we would be required to submit an application to obtain PMA approval, *de novo* classification or 510(k) clearance for certain of our LDTs unless this requirement is modified or reversed as a result of legislation or litigation. Compliance with these additional regulatory requirements would be time-consuming and expensive, potentially diverting resources from other aspects of our business, and would potentially 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. Moreover, failure to comply with these and other FDA regulations could result in legal actions, including fines and penalties. The FDA has indicated it plans to finalize the proposed rule in the second quarter of 2024, though we cannot be certain that the FDA will finalize the proposed rule on this timeline or at all. If adopted in its proposed form or otherwise, the regulation of LDTs as medical devices could have a significant negative impact on our operations and financial performance.

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 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 was reintroduced in 2023.

In the meantime, the regulatory environment for LDTs is uncertain. If FDA disagrees that tests we perform or may in the future perform are 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 a 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 LDTs, there can be no assurance that any tests we develop 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.

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 changes to medical devices that a manufacturer makes after receiving a 510(k) clearance, *de novo* classification, or PMA may trigger the need for additional FDA authorization. In the case of a 510(k)-cleared device, FDA requires a new marketing authorization for significant changes or modifications made in the design, components, method of manufacture or intended use of a device, including changes or modifications to a 510(k)-cleared device that could significantly affect the device's safety or effectiveness, or would constitute a major change or modification in the device's intended use. The type of submission needed—510(k), *de novo* classification, or PMA—will depend on the specific modification the manufacturer seeks to make. FDA expects the manufacturer to make the determination of whether a new marketing application is needed by applying existing agency guidance, but FDA may independently review, and may disagree with, our decision. If we make modifications to our marketed devices, we may be required to seek additional clearances, *de novo* classifications, or PMAs which, if not granted, would prevent us from selling the modified device. If we conclude that a modification does not require submission of a new marketing application and FDA disagrees with the decision, we may be required to submit new 510(k) notifications, *de novo* classification requests, or premarket approval applications and may be required to cease marketing of or to recall the modified devices until marketing authorization is obtained and could additionally be subject to regulatory fines or penalties. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

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, we use those components in compliance with QSR. Any failure to do so would have an adverse effect on our ability to commercialize the Ova1Plus workflow. Our suppliers that manufacture finished devices at their manufacturing facilities that we use in our products and services 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 review could be required as a condition of sale. Discontinuation of any of these kits could require identification, validation and submission to FDA 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 on 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 expect that there will be additional health reform initiatives by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or other third-party payers. 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 and Overa testing (through the Ova1Plus workflow) 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 ("AKS"), 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 penalty;

- the Federal False Claims Act civil and criminal penalties and state equivalents;
- the federal fraud, waste and abuse laws and state equivalents;
- the federal Physician Payments Sunshine Act, 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 significant civil, criminal and administrative penalties, fines, recoupment of funds received by us, exclusion from participation in federal or state healthcare programs, and the loss of various licenses, accreditations, certificates and authorizations necessary to operate our business , contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement. 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, 2023 which are subject to a full valuation allowance 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 also may limit the amount of tax credit carryforwards that can be utilized annually to offset future tax liabilities.

Our 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 on or after January 1, 2018, can be carried forward indefinitely but such federal NOL carryforwards are permitted to be used in any taxable year to offset only up to 80% of taxable income in such year. Portions of our 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 portions of our NOLs could expire before we generate 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, and certain other transactions involving our stock that are outside of our control, could cause additional ownership changes. Any current or future limitations on the use of our NOLs or tax credit carryforwards could, depending on the extent of such limitation, result in our retaining less cash during any year in which we have taxable income than we would be entitled to retain if such limitations did not apply, which could adversely impact our results of operations and financial condition.

RISKS RELATED TO INTELLECTUAL PROPERTY AND PRODUCT LIABILITY

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

One aspect of our business plan is to develop diagnostic tests based on certain biomarkers, which we have the right to utilize through licenses with our academic collaborators, such as the Johns Hopkins University School of Medicine, 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 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 THE RESTATEMENT OF OUR 2022 YEAR END FINANCIAL STATEMENTS

We face risks related to the restatement of our previously issued consolidated financial statements and financial information as of and for the fiscal year ended December 31, 2022, as well as for the interim financial information as of September 30, 2022 and for the three and nine months then ended (collectively, "the Affected Periods").

As discussed in the Note 3 to the consolidated financial statements in our Form 10-K/A filed October 26, 2023, we reached a determination to restate certain financial information and related note disclosures in our previously issued consolidated financial statements for the Affected Periods. As a result, we have become subject to a number of additional risks and uncertainties, which may affect investor confidence in the accuracy of our financial disclosures and may raise reputational issues for our business. We expect to continue to face many of the risks and challenges related to the restatement, including the processes undertaken to effect the restatement may not have been adequate to identify and correct all errors in our historical financial statements and, as a result, we may discover additional errors and our financial statements remain subject to the risk of future restatement.

We cannot assure that all of the risks and challenges described above will be eliminated or that general reputational harm will not persist. If one or more of the foregoing risks or challenges persist, our business, operations and financial condition are likely to be materially and adversely affected.

We may face litigation and other risks as a result of the restatement and material weaknesses in our internal control over financial reporting.

As part of the restatement, we identified a material weakness in our internal control over financial reporting. As a result of such material weakness, the restatement, and other matters raised or that may in the future be raised by the SEC, we face potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, or other claims arising from the restatement and the material weakness in our internal control over financial reporting and the preparation of our financial statements. As of the date of this Form 10-K, we have no knowledge of any such litigation or dispute. However, we can provide no assurance that such litigation or dispute will not arise in the future. Any such litigation or dispute, whether successful or not, could adversely affect our business, financial condition and results of operations.

The restatement of our previously issued financial statements has been time-consuming and expensive and could expose us to additional risks that could materially adversely affect our financial position, results of operations and cash flows.

We have incurred significant expenses, including audit, legal, consulting and other professional fees, in connection with the restatement of our previously issued financial statements and the ongoing remediation of material weaknesses in our internal control over financial reporting. We have implemented and will continue to implement additional processes utilizing existing resources and adding new resources as needed. To the extent these steps are not successful, we could be forced to incur additional time and expense. Our management's attention has also been diverted from the operation of our business in connection with the restatements and ongoing remediation of material weaknesses in our internal controls.

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. If our information technology systems or those third parties upon which we rely or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, process, collect, receive, store, use, transfer, make accessible, and share (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, trade secrets and other sensitive data the Company may process (collectively, sensitive information).

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.

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 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;
- 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.

Cyber-attacks, malicious internet-based activity, online and offline fraud, social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, and other similar activities or incidents threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Further, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Our mitigation efforts to date 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.

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 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 use AI/ML to assist us in making certain decisions, which is regulated by certain privacy laws. Due to inaccuracies or flaws in the inputs, outputs, or logic of the AI/ML, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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.

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 generally accepted accounting principles in the United States of America ("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, 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.

Management evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. Management concluded that our disclosure controls and procedures were not effective as of December 31, 2023, due to two material weaknesses in the internal control over financial reporting related to multiple design deficiencies.

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 related to the operation of internal controls related to information technology general controls ("ITGCs") that are used to process and record certain revenue and expense transactions and support our financial reporting processes. The internal control around ITGCs resulted in the lack of certain internal controls over these IT systems and over data and reports accumulated in such IT systems.

Management has also identified another material weakness in our revenue recognition process. Specifically, that we did not adequately design and implement our ITGCs over our revenue process. We did not adequately design controls to validate the delivery of the lab results to ordering physicians to ensure that revenue is being appropriately recognized.

While there can be no assurance that our efforts will be successful, we plan to remediate the material weaknesses during fiscal year 2024. 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.

We have had to restate our previously issued consolidated financial statements as a result of the material weakness in our internal control over financial reporting as of December 31, 2022. Additional material weaknesses 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 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, including significant, non-routine or complex transactions, we have and will continue to implement new procedures and testing for review of our accounting treatment of contracts. To remediate the material weakness in the design and implementation of our control activities over our revenue process, including effectively identifying all relevant IT applications and systems supporting the process, we have and will continue to implement controls around the rigor of the review process and retention of evidence over the review process and the identification of relevant IT applications and systems. We intend to continue to improve our operational, financial, and management controls, and our reporting systems and procedures, in order to remediate the material weaknesses.

There can be no assurance 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 control 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, when applicable, 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.

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 Market Value of Listed Securities be at least $35 million pursuant to Nasdaq Listing Rule 5550(a)(2) ("MVLS Requirement"). On July 11, 2023, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that we were not in compliance with the MVLS Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq provided us with 180 calendar days, or until January 8, 2024, to regain compliance with the MVLS Requirement. On September 12, 2023, we received notice from Nasdaq that we have regained compliance. There is no assurance that we will maintain compliance with the MVLS Requirement or any of the other Nasdaq continued listing requirements.

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 to 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.

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, we estimate that a total of five investors beneficially own approximately 40.0% of our outstanding common stock.

In addition, pursuant to a stockholders agreement we entered into in connection with a May 2013 private placement, one of our stockholders has the right to designate a director to be nominated by us to serve on our Board of Directors, and the stockholder has not exercised this right for 2023.

Furthermore, this stockholder agreement gives two investors the right to participate in future equity offerings, on the same 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 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 of our securities or distributing any of our assets other than in the ordinary course of business or repurchasing any of our outstanding securities.

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 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, 2023, the closing trading price of our common stock ranged from a high of $8.70 per share to a low of $2.40 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 (the "2013 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 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 consent pursuant to the terms of the 2013 Stockholders Agreement. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and trade secrets, data we may collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information ("Information Systems and Data").

Our cybersecurity function, which comprises, in part, our IT department, legal team, human resources team and our audit committee, helps identify, assess and manage our cybersecurity threats and risks. Our cybersecurity function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, automated tools, subscribing to and analyzing reports and services that identify cybersecurity threats, conducting vulnerability assessments to identify vulnerabilities, and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures and processes designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response, data encryption, network security controls, employee training, access controls, physical security, systems monitoring, and asset management, tracking, and disposal.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the cybersecurity function works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional services firms (including legal counsel) and cybersecurity consultants. We also use third-party service providers to perform a variety of functions throughout our business, such as hosting companies, application providers, and supply chain resources. We manage cybersecurity risks associated with our use of these providers by, for example, requesting and analyzing responses on a security questionnaire and conducting audits and risk assessments on certain vendors. In particular, our legal department performs an assessment on each vendor and based on certain criteria will have our IT team perform a security assessment.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including *"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."*

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management, including our Manager of IT Infrastructure, who has over 20 years of experience in various IT administration roles, five of which have been in cybersecurity.

Our HR department is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our CFO, working with our Manager of IT Infrastructure, is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. Our legal department is also responsible for performing a cyber risk assessment on each new vendor.

Our response process to cybersecurity incidents is designed to escalate certain incidents to members of management depending on the circumstances, including our Manager of IT Infrastructure. Our Manager of IT Infrastructure works with our incident response team to help us to mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response policy includes reporting to the board of directors committee responsible for certain cybersecurity incidents.

The Audit Committee receives periodic reports from our cybersecurity function concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The Audit Committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

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	February 28, 2027
Shelton, Connecticut	4,614 sq. ft.	Administrative offices	September 30, 2028
Palo Alto, California	2,714 sq. ft.	Administrative offices	May 31, 2024

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 28, 2024, there were 40 registered holders of record of our common stock. The closing price of our common stock on March 28, 2024 was $3.10.

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

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K

Stock Performance Graph

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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 audited Consolidated Financial Statements and related Notes thereto, included on pages F-1 through F-29 in this Annual Report on Form 10-K. The statements below contain forward-looking statements based upon current plans, expectations, and beliefs that involve risks and uncertainties. Actual results may differ materially from those contained in any forward-looking statement, due to a number of factors, including those discussed in the section of this Annual Report on Form 10-K entitled "Forward-Looking Statements" and "Item 1A. Risk Factors" in this Form 10-K. You should read these sections carefully.

Overview

We are dedicated to the discovery, development, and commercialization of noninvasive, AI-powered tests to aid in the diagnosis of gynecologic diseases.

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 the Ova1Plus workflow as compared to CA-125 on its own for all 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 2024, we plan to continue our efforts to commercialize the Ova1Plus workflow 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. 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 for launch in the second quarter of 2024, 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 could be more than three times greater than the patient population for the Ova1Plus workflow and that the longitudinal monitoring test may expand that larger patient application.

We expect that our second diagnostic algorithm, EndoCheck, will be an aid in the diagnosis of endometriomas. We are currently evaluating the potential commercial application and appropriate launch timeline of EndoCheck.

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

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 1, Basis for Presentation and Summary of Significant Accounting and Reporting Policies, of the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K. The Consolidated Financial Statements are prepared in conformity with 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 our critical accounting estimates, 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 1 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 $518,303,000 at December 31, 2023. We expect to incur a net loss in 2024 as well. In order to continue our operations as currently planned through 2024 and beyond, we will need to raise additional capital. Given the above conditions, there is substantial doubt about our 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.

Results of Operations – Year Ended December 31, 2023 as compared to Year Ended December 31, 2022

Our selected summary financial and operating data for the years ended December 31, 2023 and 2022 were as follows:

(dollars in thousands)	Year Ended December 31, 2023	2022	Increase (Decrease) Amount	%
Revenue:				
Product	$ 9,153	$ 7,970	$ 1,183	15
Genetics	1	214	(213)	(100)
Total revenue	9,154	8,184	970	12
Cost of revenue:				
Product	3,892	3,694	198	5
Genetics	-	167	(167)	-
Total cost of revenue	3,892	3,861	31	1
Gross profit	5,262	4,323	939	22
Operating expenses:				
Research and development	4,035	5,917	(1,882)	(32)
Sales and marketing	7,812	14,915	(7,103)	(48)
General and administrative	12,267	14,629	(2,362)	(16)
Total operating expenses	24,114	35,461	(11,347)	(32)
Loss from operations	(18,852)	(31,138)	12,286	(39)
Other income (expense), net:				
Change in fair value of warrant liabilities	629	1,704	(1,075)	(63)
Interest income, net	48	17	31	182
Forgiveness of DECD loan	1,000	-	1,000	-
Other income (expense), net	485	(468)	953	(204)
Total other income (expense), net	2,162	1,253	909	73
Net loss	$ (16,690)	$ (29,885)	$ 13,195	(44)

Product Revenue. Product revenue was $9.2million for the year ended December 31, 2023, compared to $8.0 million for the same period in 2022. Revenue is recognized when the test result is successfully delivered and is based on estimates of what we expect to ultimately realize. The 15% product revenue increase is due to the addition of our OvaWatch product, as well as an increase in average unit price ("AUP") per test, offset by a decrease in Ova1Plus test volume. The AUP increased to $382 for the year ended December 31, 2023, compared to $372 for the same period in 2022.

The number of OvaSuite tests performed increased 12% to approximately 23,990 tests during the year ended December 31, 2023 compared to approximately 21,423 OvaSuite tests for the same period in 2022.

The volume and AUP for the year ended December 31, 2023 and 2022 were as follows:

	Year Ended December 31, 2023	2022
Product Volume:		
Ova1Plus	20,579	21,373
OvaWatch	3,411	50
Total OvaSuite	23,990	21,423
Average Unit Price (AUP):		
Ova1Plus	$ 394	$ 373
OvaWatch	308	140
Total OvaSuite	$ 382	$ 372

Genetics Revenue. Genetics revenue was $1,000 for the year ended December 31, 2023, compared to $214,000 for the same period in 2022. Revenue was recognized when the test result was successfully delivered and was based on estimates of what we expected to ultimately realize. We discontinued offering genetics testing effective September 30, 2022.

Cost of Revenue – Product. Cost of product revenue was $3,9 million for the year ended December 31, 2023 compared to $3,7 million for the same period in 2022, representing an increase of $0.2 million, or 5%, were primarily related to variable lab supply and shipping costs due to the increase in tests performed compared to the prior year, as well as an increase in consulting costs, offset by a decrease in software costs.

Cost of Revenue - Genetics. Cost of Aspira GenetiX revenue was $0 for the year ended December 31, 2023 compared to $0.2 million for the same period in 2022, which consisted primarily of personnel costs, consulting and licensing expenses. We discontinued the genetics testing offering effective September 30, 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, 2023 decreased by $1,9 million, or 32%, compared to the same period in 2022. This decrease was primarily due to a decrease of approximately $0.8 million of costs related to our sponsored research collaboration agreements, a decrease in consulting expenses of $0.7 million and a decrease in costs due to the closure of a research and development lab in 2023. We expect research and development expenses to increase in 2024, 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 , medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the year ended December 31, 2023 decreased by $7.1 million, or 48%, compared to the same period in 2022. This decrease was primarily due to decreased employment-related expenses of $6.2 million and travel costs of $0.7 million. We expect sales and marketing expenses to increase in 2024, as we focus on the growth of our products.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel-related expenses, professional fees, including legal, finance and accounting expenses and other infrastructure expenses. General and administrative expenses for the year ended December 31, 2023 decreased by $2.4 million, or 16%, compared to the same period in 2022. This decrease was primarily due to a decrease in employment-related expenses of $2.6 million, and a decrease in outside legal costs of $0.4 million, offset by increased accounting costs of $0.4 million. We expect general and administrative expenses to decrease in 2024 due to recent personnel changes.

Change in fair value of warrant liabilities. The fair values of the warrants as of December 31, 2023, and December 31, 2022 were $1.7 million and $2.3 million , respectively, for a net change in fair value of $0.6 million.

Interest Income, net. We had net interest income of $48,000 and $17,000, respectively, for the years ended December 31, 2023 and 2022. The change in the net interest income was primarily related to lower interest on the DECD loan after the forgiveness of $1.0 million and an increase in the interest earned on our money market accounts.

Forgiveness of DECD loan. Forgiveness of the DECD loan increased $1.0 million, compared to the same period in 2022. $1.0 million of our loan with the State of Connecticut Department of Economic and Community Development (the "DECD") was partially forgiven in 2023.

Other Income (Expense), net. Other income for the year ended December 31, 2023 increased by $2.0 million, compared to the same period in 2022. The increase related primarily to one-time transactions, including the receipt of Employee Retention Tax Credits of $0.3 million and the receipt of insurance reimbursements of $0.3 million in 2023 and issuance costs related to warrants in 2022 of $0.6 million. The increase was offset by issuance costs associated with an equity line of credit of $0.3 million in 2023.

Cash Flows The following table summarizes our cash flows for the periods ended December 31, 2023 and 2022.

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Net cash (used in) provided by:		
Operating activities	$ (15,894)	$ (31,068)
Investing activities	(24)	(232)
Financing activities	5,216	7,427
Net decrease in cash, cash equivalents and restricted cash	$ (10,702)	$ (23,873)

Net cash used in operating activities was $15.9 million for the year ended December 31, 2023, resulting primarily from the net loss reported of $16.7 million , the forgiveness of our DECD loan of $1,000,000 and changes in fair value of warrant liabilities in the amount of approximately $0.6, primarily offset by $1.7 million related to non-cash stock compensation expense and $0.6 million related to changes in prepaid expenses and other assets.

Net cash used in operating activities was $31.1 million for the year ended December 31, 2022, resulting primarily from the net loss reported of $29.9 million, changes in fair value of warrant liabilities of approximately $1.7 million and changes in accrued liabilities of $1.8 million and changes in accounts payable of $0.6 million, primarily offset by $2.4 million related to non-cash stock compensation expense.

Net cash used in investing activities was $24,000 and $232,000 for the years ended December 31, 2023 and 2022, respectively, which consisted primarily of property and equipment purchases.

Net cash provided by financing activities was $5.2 million for the year ended December 31, 2023, related primarily to a registered direct offering resulting in net proceeds of $4.1 million, after deducting placement agent costs and other expenses of $0.6 million, net proceeds of $68,000 related to an at-the market offering, after deducting transaction-related offering costs of $0.1 million, and an equity line of credit offering of $1.2 million, partially offset by principal payments on the DECD loan of $0.1 million. Net cash provided by financing activities was $7.4 million for the year ended December 31, 2022, which resulted primarily from a follow-on equity offering, resulting in net proceeds to us of approximately $7.7 million, after deducting underwriting discounts and offering expenses, including $0.6 million of expenses attributed to warrants that were included in the net loss.

We have significant NOL carryforwards as of December 31, 2023 which are subject to a full valuation allowance 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 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 also may limit the amount of tax credit carryforwards that can be utilized annually to offset tax liabilities.

Our 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 on or after January 1, 2018, can be carried forward indefinitely but such federal NOL carryforwards are permitted to be used in any taxable year to offset up to 80% of taxable income in such year. Portions of our state NOLs will expire in varying amounts from 2023 through 2037 if not utilized. Our ability to use our NOLs will be dependent on our ability to generate taxable income, and the portions of our NOLs could expire before we generate sufficient taxable income.

Our ability to use our NOL carryforwards to offset taxable income 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 limitations may result in the expiration of a portion of our NOL carryforwards before utilization. Due to the existence of a full valuation allowance against our remaining NOLs, it is not expected that Section 382 limitations will have an impact on our results of operations or financial position.

Liquidity and Capital Resources

We plan to continue to expend resources selling and marketing or ovarian cancer and endometriosis offerings 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. We have incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately $518.3 million as of December 31, 2023. We also expect to incur a net loss and negative cash flows from operations for 2024. In order to continue our operations as currently planned through 2024 and beyond, we will need to raise additional capital, which may include public or private equity offerings, debt financing, collaborations, licensing arrangements. Given the above conditions, there is substantial doubt about our 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.

Contractual Obligations

Loan Agreement

In March 2016, we 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 we may borrow up to $4,000,000 from the DECD.

The loan may be prepaid at any time without premium or penalty. We received an initial disbursement of $2,000,000 on April 15, 2016 under the DECD Loan Agreement. As we 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, on December 3, 2020, we received a disbursement of the remaining $2,000,000 available under the DECD Loan Agreement.

Under the terms of the DECD Loan Agreement, we were eligible for forgiveness of up to $1,500,000 of the principal amount of the loan had we achieved certain job creation and retention milestones by December 31, 2022. On June 26, 2023, we were notified by the DECD that we had satisfied all job creation and retention requirements under the loan agreement to receive forgiveness of $1,000,000. If we fail to 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 of December 31, 2023, the remaining balance outstanding under the DECD Loan Agreement is approximately $1,596,000, net of issuance costs.

Operating Leases

As of December 31, 2023, we are engaged in three lease agreements. Our Austin, Texas lease renewal agreement has a term of 37 months and expires on February 28, 2027, with the option to extend the lease for an additional three years. Our Shelton, Connecticut lease renewal agreement has a five-year term and expires on September 30, 2028, with a five-year renewal option. Our Palo Alto, California sublease agreement has a term of 13 months and expires on May 31, 2024, with no option for renewal with the sublessor.

Non-cancelable Royalty Obligations and Other Commitments

We are a party to an amended research collaboration agreement with The Johns Hopkins University School of Medicine under which we license 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, 2023 and 2022 totaled $324,000 and $318,000, respectively, as recorded in cost of revenue in the consolidated statements of operations.

Business Agreements

In August 2022, we 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 are due from us to the counterparties upon successful completion of certain deliverables. During the year ended December 31, 2023, approximately $215,000 has been recorded as research and development expense in our consolidated financial statement of operations for the project. During the year ended December 31, 2022, approximately $868,000, was recorded as research and development expense in our consolidated financial statement of operations for the project. From the inception of the Dana-Faber, Brigham, Lodz Research Agreement through December 31, 2023, research and development expenses in the cumulative amount of $1,083,000 have been recorded. From the inception of the Dana-Faber,

Brigham, Lodz Research Agreement through December 31, 2023, we made payments totaling $1,040,000. Additional payments of $212,000 are due to the collaboration partners in 2024 upon completion of certain deliverables estimated to occur during 2024.

On March 20, 2023, we entered into a licensing agreement with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz (the "Ovarian Cancer License Agreement") under which the Company will license certain of its intellectual property to be used in our OvaSuite product portfolio. Under the terms of the Ovarian Cancer License Agreement, we paid an initial license fee of $75,000 and then will pay a license maintenance fee of $50,000 on each anniversary of the date, as well as non-refundable royalty payments of up to $1,350,000 based on certain regulatory approvals and commercialization milestones and further royalty payments based on the net sales of our products included. No milestones have been reached as of December 31, 2023, and no royalty payments have been paid to date.

Common Stock

On February 10, 2023, we entered into a Controlled Equity Offering Sales Agreement (the "Cantor 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 (the "Placement Shares"). On July 19, 2023, we delivered written notice to Cantor that we were suspending the prospectus supplement, dated February 10, 2023, related to our common stock issuable under the Cantor Sales Agreement. We will not make any sales of common stock pursuant to the Cantor Sales Agreement unless and until a new prospectus supplement is filed with the SEC. The Cantor Sales Agreement remains in full force and effect during the suspension.

During the year ended December 31, 2023, we sold 35,552 shares of the Placement Shares, respectively, as adjusted for the Reverse Stock Split, for gross proceeds of approximately $211,000. For the year ended December 31, 2023, we recorded $134,000 as an offset to additional paid-in capital representing transaction-related offering costs of 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.

During the year ended December 31, 2023, we sold 360,943 shares under the LPC Purchase Agreement for gross proceeds of approximately $1,177,000. We incurred approximately $329,000 of costs related to the execution of the LPC Purchase Agreement, all of which are reflected in our consolidated financial statements. Of the total costs incurred, approximately $258,000 was paid in common stock to Lincoln Park for a commitment fee and $30,000 was paid for Lincoln Park expenses. These transaction costs were included in other expense on our consolidated statement of operations. Approximately $41,000 was incurred for legal fees during the year ended December 31, 2023 and were included in general and administrative expenses on our consolidated statement of operations.

On July 24, 2023, we completed a follow-on equity offering resulting in net proceeds of approximately $4.2 million.

Under the terms of the July 24, 2023 follow-on equity offering, we agreed not to sell shares under the LPC Purchase Agreement for 90 days. On October 30, 2023, we resumed selling shares under the LPC Purchase Agreement, exercising the option for an Accelerated Purchase as allowed under the LPC Purchase Agreement. As of March 22, 2024, we have sold 111,369 shares for aggregate gross proceeds of approximately $400,000 subsequent to the year ended December 31, 2023.

On January 26, 2024, we completed a follow-on equity offering resulting in net proceeds of approximately $4.8 million. Under the terms of that agreement, we agreed not to sell shares under the LPC Purchase Agreement for 90 days.

In connection with a private placement offering of common stock and warrants we completed in May 2013, we entered into the 2013 Stockholders Agreement which, among other things, gives two of the primary investors in that offering the right to participate in any of our future equity offerings on the same price and terms as other investors. In addition, the 2013 Stockholders Agreement prohibits us from taking certain material actions without the requisite consent. These material actions include:

- Making any acquisition with a value greater than $2 million;
- Offering, selling or issuing any securities senior to our common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to our common stock;
- 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 of our securities or distributing any of our assets other than in the ordinary course of business or repurchasing any of our outstanding securities.

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.

We have incurred significant net losses and negative cash flows from operations since inception. At December 31, 2023 we had an accumulated deficit of $518.3 million and stockholders' deficit of $2.4 million. As of December 31, 2023, we had $2.6 million of cash and cash equivalents (excluding restricted cash of $258,000), and $5.1 million of current liabilities. Working capital was $0.2 million at December 31, 2023. 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 2024.

We expect to incur a net loss and negative cash flows from operations in 2024.

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 product adoption by physicians and patients;
- the rate of product adoption by healthcare systems and large physician practices of the decentralized distribution agreements;
- the insurance payer community's acceptance of and reimbursement for our products;
- our plans to acquire or invest in other products, technologies and businesses; and
- the potential need to add study sites to access additional patients to maintain clinical timelines;

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.

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, 2023 and 2022, consolidated statements of operations for the years ended December 31, 2023 and 2022, consolidated statements of changes in stockholders' equity for the years ended December 31, 2023 and 2022, consolidated statements of cash flows for the years ended December 31, 2023 and 2022 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-29.

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

Our senior management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) designed

to ensure that information required to be disclosed by us in the reports that 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 forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management, including our Chief Executive Officer and Chief Financial Officer, performed an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2023, our disclosure controls and procedures were not effective. This was due to two material weaknesses in the internal control over financial reporting that were identified as of December 31, 2023 related to multiple deficiencies and a lack of timely operation of certain internal controls over financial reporting and disclosure.

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, 2023. 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 identified a material weakness related to the operation of internal controls related to information technology general controls ("ITGCs") that are used to process and record certain revenue and expense transactions and support our financial reporting processes. The internal control around ITGCs resulted in the lack of certain internal controls over these IT systems and over data and reports accumulated in such IT systems.

Another material weakness was identified with respect to the design and implementation of our control activities over our revenue process. We did not adequately design controls to validate the delivery of the lab results to ordering physicians to ensure that revenue is being appropriately recognized.

These have resulted in material weaknesses in our internal control over financial reporting as of December 31, 2023. 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, 2023, our internal control over financial reporting was not effective.

This 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, 2023 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 our Annual Report on Form 10-K.

Remediation Activities

In order to address the material weaknesses in internal control over financial reporting described above, management is in the process of implementing remediation activities, with direction from the audit committee. The activities that we have taken and are taking are listed below.

- Retained an internal controls specialist to complement the skills of the existing accounting and financial reporting staff, as well as implement key controls to improve business processes, including revenue and the IT environment.
- Completed a preliminary process to identify all information technology applications that support our financial reporting processes and assess the risk of misstatement associated with each.
- Planning a comprehensive review of the design and performance of internal controls related to information technology applications, including user access and program change controls.
- Enhanced controls that require the assessment of service organization controls prior to implementation and on an annual basis.
- Retained 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, particularly for certain significant, non-routine or complex transactions, including warrant valuation.
- Providing additional training and continuing education to accounting staff regarding SEC requirements and required disclosures under GAAP.
- Enhancing the design of and implement controls around the rigor of the review process, and retention of sufficient appropriate evidence over the revenue process.

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 enhancements related to our ITGCs around the material weaknesses described above, which include the assessment of material transactions and accounting resources and training, 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 three months ended December 31, 2023 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 our directors, committees of our Board of Directors, our director nomination process, and our executive officers appearing under the heading "Election of Directors," "Corporate Governance," "Management", "Security Ownership of Certain Beneficial 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 2024 (the "2024 Proxy Statement") is incorporated by reference.

We have 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. Our Code of Business Conduct and Ethics is available on our website at ir.aspirawh.com/corporate-governance. Within the time period required by the SEC and Nasdaq, we will post on our website at ir.aspirawh.com/corporate-governance any amendment to our 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 2024 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 2024 Proxy Statement is incorporated by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section titled "Equity Compensation Plan Information" in the 2024 Proxy Statement and is incorporated herein 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 2024 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 2024 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-29.

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 Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Fourth Amended and Restated Certificate of Incorporation of Aspira Women's Health Inc. dated January 22, 2010	8-K	000-31617	3.1	January 25, 2010	
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation, effective June 19, 2014	10-Q	001-34810	3.2	August 14, 2014	
3.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated June 11, 2020	8-K	001-34810	3.1	June 11, 2020	
3.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Aspira Women's Health Inc, dated February 7, 2023	8-K	001-34810	3.1	February 7, 2023	
3.5	Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock	8-K	001-34810	4.1	April 17, 2018	
3.6	Amended and Restated Bylaws of Aspira Women's Health Inc., effective February 23, 2022	8-K	001-34810	3.1	February 28, 2022	
4.1	Form of Aspira Women's Health Inc.'s (formerly Ciphergen Biosystems, Inc.) Common Stock Certificate	S-1/A	333-32812	4.1	August 24, 2000	
4.2	Securities Purchase Agreement dated May 8, 2013, by and among Aspira Women's Health Inc. (formerly Vermillion, Inc.) and the purchasers identified therein	8-K	001-34810	10.1	May 14, 2013	
4.3	Stockholders Agreement dated May 13, 2013, by and among Vermillion, Inc., Oracle Partners, LP, Oracle Ten Fund Master, LP, Jack W. Schuler and other purchasers named therein	8-K	001-34810	10.2	May 14, 2013	
4.4	Amended and Restated Promissory Note #1 by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective April 3, 2020	10-K	001-34810	4.4	April 7, 2020	
4.5	Amended and Restated Promissory Note #2 by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective April 3, 2020	10-K	001-34810	4.5	April 7, 2020	
4.6	Form of Indenture	S-3	333-252267	4.7	January 20, 2021	
4.7	Description of Aspira Women's Health Inc.'s Securities Pursuant to Section 12 of the Securities Exchange Act of 1934					√
4.8	Form of Warrant 2022	8-K	001-34810	4.1	August 24, 2022	
4.9	Form of Warrant Amendment to Common Stock Purchase Warrant	8-K	001-34810	4.3	January 26, 2024	
4.10	Form of Pre-Funded Warrant 2024	8-K	001-34810	4.1	January 26, 2024	
4.11	Form of Warrant 2024	8-K	001-34810	4.2	January 26, 2024	
4.12	Purchase Agreement, dated March 28, 2023, by and between Aspira Women's Health Inc. and Lincoln Park Capital Fund, LLC.	8-K	001-34810	10.1	March 30, 2023	
4.13	Registration Rights Agreement, dated as of March 28, 2023, by and between Aspira Women's Health Inc. and Lincoln Park Capital Fund, LLC.	8-K	001-34810	10.2	March 30, 2023	
10.1	Form of Proprietary Information Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and certain of its employees #	S-1/A	333-32812	10.9	August 24, 2000	
10.2	Securities Purchase Agreement, dated July 20, 2023, by and between Aspira Women's Health Inc. and the purchasers identified therein	8-K	001-34810	10.1	July 24, 2023	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date	Filed Herewith
10.3	Vermillion, Inc. Second Amended and Restated 2010 Stock Incentive Plan (as amended effective June 21, 2018) #	8-K	001-34810	10.1	June 27, 2018	
10.4	Form of Vermillion, Inc. Stock Option Award Agreement through December 31, 2021 #	10-K	001-34810	10.7	March 28, 2019	
10.5	Form of Vermillion, Inc. Stock Option Award Agreement after January 1, 2022 #	10-Q	001-34810	10.1	August 10, 2022	
10.6	Form of Aspira Women's Health Inc Stock Option Award Agreement #	10-Q	001-34810	10.4	August 10, 2022	
10.7	Form of Vermillion, Inc. Restricted Stock Award Agreement through December 31, 2021#	10-K	001-34810	10.8	March 28, 2019	
10.8	Form of Vermillion, Inc. Restricted Stock Award Agreement after January 1, 2022#	10-Q	001-34810	10.2	August 10, 2022	
10.9	Form of Aspira Women's Health Inc Restricted Stock Award Agreement #	10-Q	001-34810	10.5	August 10, 2022	
10.10	Aspira Women's Health Inc. 2019 Stock Incentive Plan #	10-Q	001-34810	10.3	August 10, 2022	
10.11	Form of Vermillion, Inc. Stock Option Award Agreement (non-employee) #	10-Q	001-34810	10.6	August 10, 2022	
10.12	Form of Aspira Women's Health Inc. Stock Option Award Agreement (non-employee) #	10-Q	001-34810	10.7	August 10, 2022	
10.13	Testing and Services Agreement between Vermillion, Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated, dated as of March 11, 2015	10-Q	001-34810	10.5	May 12, 2015	
10.14	Amendment No. 1 to the Testing and Services Agreement between Vermillion, Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated dated April 10, 2015	10-Q	001-34810	10.6	May 12, 2015	
10.15	Amendment No. 2 to Testing and Services Agreement, executed as of March 7, 2017 and effective as of March 11, 2017, by and among Vermillion, Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated	8-K	001-34810	10.1	March 13, 2017	
10.16	Amendment No. 3 to Testing and Services Agreement, executed as of March 1, 2018 by and among Vermillion, Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated	8-K	001-34810	10.1	March 6, 2018	
10.17	Amendment No. 4 to Testing and Services Agreement, executed as of March 11, 2020 by and among Vermillion, Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated	8-K	001-34810	10.1	March 17, 2020	
10.18	Amendment No. 5 to Testing and Services Agreement, executed as of December 6, 2022 by and among Aspira Women's Health Inc., Aspira Labs, Inc. and Quest Diagnostics Incorporated					✓
10.19	Assistance Agreement by and between the State of Connecticut, acting by and through the Department of Economic and Community Development and Vermillion, Inc. effective March 22, 2016	10-Q	001-34810	10.1	May 16, 2016	
10.20	Patent Security Agreement by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective March 22, 2016	10-Q	001-34810	10.3	May 16, 2016	
10.21	Security Agreement by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective March 22, 2016	10-Q	001-34810	10.4	May 16, 2016	
10.22	First Amendment to the Assistance Agreement by and between the State of Connecticut, acting by and through the Department of Economic and Community Development and Vermillion, Inc. dated March 7, 2018	10-K	001-34810	10.21	March 13, 2018	
10.23	Second Amendment to the Assistance Agreement by and between the State of Connecticut, acting by and through the Department of Economic and Community Development and Vermillion, Inc. dated April 3, 2020	10-K	001-34810	10.22	April 7, 2020	
10.24	Promissory Note, dated May 1, 2020, between Vermillion, Inc. and BBVA USA	8-K	001-34810	10.1	May 7, 2020	
10.25	Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Nicole Sandford effective March 1, 2023# †	8-K	001-34810	10.1	March 2, 2023	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date	Filed Herewith
10.26	Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Minh Merchant, effective March 28, 2023#†	10-K	001-34810	10.32	March 30, 2023	
10.27	Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Torsten Hombeck effective March 13, 2024# †	8-K	001-34810	10.1	March 25, 2024	
10.28	License Agreement between Aspira Women's Health Inc. and Dana-Farber Cancer Institute, Inc. effective March 20, 2023					√
10.29	Sales Agreement between Aspira Women's Health Inc, and Cantor Fitzgerald & Co., dated February 10, 2023	8-K	001-34810	1.1	February 10, 2023	
21.0	Subsidiaries of Registrant	10-K	001-34810	21.0	March 31, 2022	
23.1	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm					√
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					√
97.1	Aspira Women's Health Incentive Compensation Recoupment Policy					√
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

Report of Independent Registered Public Accounting Firm

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

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, 2023 and 2022, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of 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, 2023 and 2022, 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 Matter

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

Revenue Recognition – Determination of Transaction Price for Product Revenue

As described in Note 1 to the consolidated financial statements, the Company recognizes product revenue upon completion of the test and delivery of results to the physician based on estimates of the amounts that will ultimately be realized. When determining the amount of revenue to be recognized, management applies judgment to determine the transaction price, which affects the amount of revenue recognized. The Company's product revenue for the year ended December 31, 2023 was $9.2 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 of payment, payer coverage and the existence of reimbursement contracts. Auditing these inputs was especially challenging due to the extent of audit effort required to address these matters.

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.

/s/ BDO USA, P.C

We have served as the Company's auditor since 2012.

Boston, Massachusetts
March 29, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,597	$ 13,306
Accounts receivable, net of reserves of $15 and $9, as of December 31, 2023 and December 31, 2022, respectively	1,459	1,245
Prepaid expenses and other current assets	997	1,442
Inventories	227	316
Total current assets	5,280	16,309
Property and equipment, net	165	368
Right-of-use assets	528	282
Restricted cash	258	251
Other assets	31	163
Total assets	$ 6,262	$ 17,373
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 1,261	$ 881
Accrued liabilities	2,863	3,402
Current portion of long-term debt	166	403
Short-term debt	670	764
Current maturities of lease liabilities	159	77
Total current liabilities	5,119	5,527
Non-current liabilities:		
Long-term debt	1,430	2,315
Non-current maturities of lease liabilities	427	272
Warrant liabilities	1,651	2,280
Total liabilities	8,627	10,394
Commitments and contingencies (Note 6)		
Stockholders' (deficit) equity:		
Common stock, par value $0.001 per share, 200,000,000 and 150,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 10,645,049 and 8,306,326 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	11	8
Additional paid-in capital	515,927	508,584
Accumulated deficit	(518,303)	(501,613)
Total stockholders' (deficit) equity	(2,365)	6,979
Total liabilities and stockholders' (deficit) equity	$ 6,262	$ 17,373

See accompanying notes to consolidated financial statements

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

	Year Ended December 31,	
	2023	**2022**
Revenue:		
Product	$ 9,153	$ 7,970
Genetics	1	214
Total revenue	9,154	8,184
Cost of revenue:		
Product	3,892	3,694
Genetics	-	167
Total cost of revenue	3,892	3,861
Gross profit	5,262	4,323
Operating expenses:		
Research and development	4,035	5,917
Sales and marketing	7,812	14,915
General and administrative	12,267	14,629
Total operating expenses	24,114	35,461
Loss from operations	(18,852)	(31,138)
Other income (expense), net:		
Change in fair value of warrant liabilities	629	1,704
Interest income, net	48	17
Forgiveness of DECD loan	1,000	-
Other income (expense), net	485	(468)
Total other income (expense), net	2,162	1,253
Net loss	$ (16,690)	$ (29,885)
Net loss per share - basic and diluted	$ (1.81)	$ (3.85)
Weighted average common shares used to compute basic and diluted net loss per common share	9,233,306	7,769,109

See accompanying notes to consolidated financial statements

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

	Common Stock				
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance at December 31, 2021	7,475,916	$ 7	$ 501,893	$ (471,728)	$ 30,172
Net loss	-	-	-	(29,885)	(29,885)
Common stock issued in conjunction with exercise of stock options	1,533	-	13	-	13
Common stock and warrants issued in conjunction with follow-on public offering, net of issuance costs	800,000	1	4,265	-	4,266
Common stock issued for vested restricted stock awards	28,877	-	362	-	362
Stock-based compensation expense	-	-	2,051	-	2,051
Balance at December 31, 2022	8,306,326	$ 8	$ 508,584	$ (501,613)	$ 6,979
Net loss	-	-	-	(16,690)	(16,690)
Common stock issued under an at the market offering agreement, net of issuance costs	35,552	-	68	-	68
Common stock issued under an equity line of credit agreement	360,943	-	1,177	-	1,177
Common stock issued for entering into equity line of credit with Lincoln Park	47,733	-	258	-	258
Common stock issued under a registered direct offering, net of issuance costs	1,694,820	2	4,117	-	4,119
Common stock issued for vested restricted stock awards	199,699	1	814	-	815
Stock-based compensation expense	-	-	909	-	909
Fractional shares adjustment related to reverse stock split	(24)	-	-	-	-
Balance at December 31, 2023	10,645,049	$ 11	$ 515,927	$ (518,303)	$ (2,365)

See accompanying notes to consolidated financial statements

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (16,690)	$ (29,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	(9)	4
Depreciation and amortization	199	264
Stock-based compensation expense	1,724	2,414
Change in fair value of warrant liabilities	(629)	(1,704)
Other expenses representing transaction costs allocated to the issuance of warrants	-	574
Loss on impairment and disposal of property and equipment	28	64
Forgiveness of DECD loan	(1,000)	-
Financing expense for entering into equity line of credit with Lincoln Park	258	-
Changes in operating assets and liabilities:		
Accounts receivable	(214)	(218)
Prepaid expenses and other assets	577	33
Inventories	89	(142)
Accounts payable	380	(620)
Accrued liabilities	(539)	(1,838)
Other liabilities	(68)	(14)
Net cash used in operating activities	(15,894)	(31,068)
Cash flows from investing activities:		
Purchase of property and equipment	(24)	(232)
Net cash used in investing activities	(24)	(232)
Cash flows from financing activities:		
Principal repayment of DECD loan	(148)	(261)
Proceeds from issuance of common stock from exercise of stock options	-	13
Proceeds from at the market offering	202	-
Payment of issuance costs for at the market offering	(134)	-
Proceeds from equity line of credit	1,177	-
Proceeds from registered direct offering	4,716	-
Payment of issuance costs for registered direct offering	(597)	-
Proceeds from public offering	-	9,000
Payment of issuance costs for public offering	-	(1,325)
Net cash provided by financing activities	5,216	7,427
Net decrease in cash, cash equivalents and restricted cash	(10,702)	(23,873)
Cash, cash equivalents and restricted cash, beginning of year	13,557	37,430
Cash, cash equivalents and restricted cash, end of year	$ 2,855	$ 13,557
Reconciliation to Consolidated Balance Sheet:		
Cash and cash equivalents	$ 2,597	$ 13,306
Restricted cash	258	251
Unrestricted and restricted cash and cash equivalents	$ 2,855	$ 13,557
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 45	$ 77
Supplemental disclosure of noncash investing and financing activities:		
Net increase in right-of-use assets	$ 318	$ -
Fair value of warrants issued in conjunction with common stock offering	-	3,984

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) the Ova1Plus workflow, which uses Ova1, a qualitative serum 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, as the primary test and Overa, a second-generation biomarker test intended to maintain Ova1's high sensitivity while improving specificity, as a reflex for Ova1 intermediate range results, leveraging the strengths of Ova1's MIA sensitivity and Overa's (MIA2G) specificity to reduce incorrectly elevated results; and (2) OvaWatch, an LDT intended to assist in the initial clinical assessment of malignancy risk in all women thought to have an indeterminate or benign adnexal mass. Overa is currently not offered except as a reflex test performed as part of the Ova1Plus workflow. Collectively, these tests are referred to and marketed as OvaSuite. For the year ended December 31, 2023, 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 marketing and distribution agreements with BioReference Health, LLC and ARUP Laboratories.

Going Concern

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 $518.3 million and working capital of $0.2 million as of December 31, 2023. For the year ended December 31, 2023, the Company incurred a net loss of $16.7 million and used cash in operations of $15.9 million. The Company also expects to incur a net loss and negative cash flows from operations for 2024. In order to continue our operations as currently planned through 2024 and beyond, the Company will need to raise additional capital. 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 (to the extent that the Company raises additional funds by issuing equity securities, the Company's stockholders may experience significant dilution. 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 2024. 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. On May 26, 2023, the Company received notice from Nasdaq that it had regained compliance.

On July 11, 2023, the Company received a second deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying the Company that, for the 30 consecutive business days prior to the date of the deficiency letter, the Company's Market Value of Listed Securities was below the minimum of $35 million requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "MVLS Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq provided the Company with 180 calendar days, or until January 8, 2024, to regain compliance with the MVLS Requirement. On September 12, 2023, the Company received notice from Nasdaq that it had regained compliance. There is no assurance that the Company will maintain compliance with the MVLS Requirement or any of the other Nasdaq continued listing requirements.

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.

Restricted Cash

Restricted cash consists of a security deposit for a credit card financing arrangement. The restriction on the cash will be removed when the Company closes its credit card account.

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, accounts payable, debt and warrant liability. Cash and cash equivalents, restricted cash, accounts receivable, and accounts payable are considered Level 1 due to their short-term nature and their market interest rates. Warrant liability is considered Level 2 and is recorded at fair value at the end of each reporting period. Debt is considered Level 3, which the Company does not record at fair value.

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 grants credit to customers in the normal course of business and the resulting trade receivables are stated at their net realizable value. The Company maintains an allowance for credit losses based upon the expected collectability of accounts receivable, such as the historical collection cycle. Amounts are written off against the allowances for credit losses when the Company determines that a customer account is not collectable. We believe our exposure to concentrations of credit risk is limited due to the diversity of our payer base.

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, 2023 and 2022, there were no material 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, 2023 and 2022.

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 or 2023, 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 $341,000 and $410,000 for the years ended December 31, 2023 and 2022, 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. These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore are subject to management's judgment. 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.

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.

2023 Reverse Stock Split

At the Company's annual meeting on May 9, 2023, the stockholders of the Company approved the proposal to authorize the Board of Directors in its discretion, without further authorization of the Company's stockholders, to amend the Company's Certificate of Incorporation to effect a reverse split of the Company's common stock by a ratio of between one-for-ten and one-for-twenty. On May 9, 2023, the Company's board of directors approved a one-for-fifteen reverse stock split of the Company's common stock without any change to its par value, which became effective on May 12, 2023. All references to share and per share amounts for all periods presented in these consolidated financial statements have been retrospectively restated to reflect the Reverse Stock Split and proportional adjustment of the preferred stock conversion ratio. Par values were not adjusted.

Government Assistance

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). One provision within the CARES Act provided an *Employee Retention Credit* ("ERC"), which allows for employers to claim a refundable tax credit against the employer share of Social Security tax equal to 50% of the qualified wages paid to employees from March 13, 2020 through December 31, 2020. The ERC was subsequently expanded in 2021 for employers to claim a refundable tax credit for 70% of the qualified wages paid to employees from January 1, 2021 through September 30, 2021.

The Company qualified for federal government assistance through the ERC. In August 2023, we received approximately $347,000 from the Internal Revenue Service for payroll tax refunds for 2020. The Company recorded the receipt as other income in its consolidated statements of operations.

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 right-of-use assets and liabilities. Lease liabilities and their corresponding right-of-use 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, does not recognize a right-of-use 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, 2023 and 2022.

Segment Reporting

The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer. The CODM 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 was effective January 1, 2023 for smaller reporting companies, which includes the Company. The Company adopted the new standard on January 1, 2023.The adoption of ASU 2016-13 did not have any impact on the Company's results of operations, financial position, or cash flows.

In March 2020, the 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 affect ASU No. 2016-13, *Financial instruments – credit losses (Topic 326): measurement of credit losses on financial statements*. Effective dates of issue 6 and 7 were the same as the effective date of ASU No. 2016-13. The Company adopted the new standard on January 1, 2023. The adoption of this standard did not have a material impact on the Company's results of operations, financial position, or cash flows.

In August 2020, the FASB issued ASU 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 is scheduled to be effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company does not expect this standard to have a material impact on its consolidated results of operations, financial position, or cash flows.

In June 2022, the FASB issued ASU No. 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* ("ASU 2022-03") to clarify guidance in Topic 820 on the fair value measurement of an equity security that is subject to a contractual sale restriction and also requires specific disclosures related to an equity security. ASU 2022-03 is scheduled to be effective for fiscal years beginning after December 15, 2024, including interim periods within those fiscal years. Early adoption is permitted. The Company does not expect a material impact as a result of this standard on its results of operations, financial position, or cash flows.

In March 2023, the FASB issued ASU No. 2023-01, *Leases (Topic 842): Common Control Arrangements* ("ASU 2023-01"). ASU 2023-01 clarified the accounting for leasehold improvements for leases under common control. The guidance is scheduled to be effective for fiscal years beginning after December 15, 2024, including interim periods within those fiscal years. Early adoption is permitted. The Company is in the process of evaluating the potential impact of the adoption of this standard on its results of operations, financial position, or cash flows.

In October 2023, the FASB issued ASU No. 2023-06, D*isclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative* ("ASU 2023-06"). The amendments in this ASU are expected to clarify or improve disclosure and presentation requirements of a variety of ASC topics by aligning them with the SEC's regulations. ASU 2023-06 will become effective for each amendment on the effective date of the SEC's corresponding disclosure rule changes. The Company does not expect ASU 2023-06 will have a material impact on its results of operations, financial position, or cash flows.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07") to update reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. This ASU requires disclosure of significant segment expenses that are regularly provided to the CODM and included within the reported measure of a segment's profit or loss,

requires interim disclosures about a reportable segment's profit or loss and assets that are currently required annually, requires disclosure of the position and title of the CODM, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, and contains other disclosure requirements. ASU 2023-07 is scheduled to be effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted. The Company is in the process of evaluating the potential impact the adoption of ASU 2023-07 will have a material its results of operations, financial position, or cash flows.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09") that addresses requests for improved income tax disclosures from investors that use the financial statements to make capital allocation decisions. Public entities must adopt the new guidance for fiscal years beginning after December 15, 2024. The amendments in this ASU must be applied on a retrospective basis to all prior periods presented in the financial statements and early adoption is permitted. The Company does not expect ASU 2023-09 will have a material impact on its results of operations, financial position, or cash flows.

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 December 8, 2022, 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 2022 amendment was to add OvaWatch to the U.S testing services for Quest Diagnostics customers and to extend the term of the agreement from March 11, 2023 to December 31, 2023. Under the terms of the agreement, as amended, the Company is required 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, 2023, the Company has $346,820 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, 2023 and 2022 were as follows:

(in thousands)	Estimated Useful Life	December 31, 2023	December 31, 2022
Machinery and equipment	3 - 5 years	$ 363	$ 891
Computer equipment and software	3 years	1,377	1,386
Furniture and fixtures	5 years	189	181
Leasehold improvements	(1)	52	721
Gross property and equipment		1,981	3,179
Accumulated depreciation and amortization		(1,816)	(2,811)
Property and equipment, net		$ 165	$ 368

(1) Lesser of remaining lease term or estimated useful life

Depreciation expense for property and equipment was $199,000 and $265,000 for the years ended December 31, 2023 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 believed it represented the most appropriate fair value of the asset group. There were no impairment charges for the year ended December 31, 2023.

NOTE 5: ACCRUED LIABILITIES

The components of accrued liabilities as of December 31, 2023 and 2022 were as follows:

(in thousands)	December 31, 2023	December 31, 2022
Payroll and benefits related expenses	$ 1,189	$ 1,803
Collaboration and research agreements expenses	217	404
Professional services	951	556
Other accrued liabilities	506	639
Total accrued liabilities	$ 2,863	$ 3,402

NOTE 6: COMMITMENTS, CONTINGENCIES AND DEBT

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 would have occurred 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 was eligible for forgiveness of up to $1,500,000 of the principal amount of the loan if it was able to achieve certain job creation and retention milestones by December 31, 2022. On June 26, 2023, the Company was notified by the DECD that the Company satisfied all job creation and retention requirements under the loan agreement to receive forgiveness of $1,000,000. During the year ended December 31, 2023, the Company recorded the $1,000,000 as other income in the statement of operations. If the Company fails to maintain its 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.

On June 6, 2023, the Company was granted a deferral of interest and principal payments on a portion of the remaining outstanding balances through December 1, 2023. On January 30, 2024, the Company was granted an additional deferral of interest and principal payments on a portion of the remaining outstanding balances through June 1, 2024. The Company determined the loan deferrals met the definition of a troubled debt restructuring under ASC 470-60, *Troubled Debt Restructurings by Debtors*, as the Company was experiencing financial difficulties and the lenders granted a concession. The future undiscounted cash flows of the DECD loan after the loan deferrals exceeded the carrying value of the DECD loan prior to the loan deferrals. As such no gain was recognized as a result of the deferrals.

Long-term debt consisted of the following:

(in thousands)	December 31, 2023	December 31, 2022
DECD loan, net of issuance costs	$ 1,596	$ 2,718
Less: Current portion, net of issuance costs	(166)	(403)
Total long-term debt, net of issuance costs	$ 1,430	$ 2,315

As of December 31, 2023, 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 $8,000. Debt related to the insurance promissory note of $670,000, as described below, is not included in the following table due to the insurance promissory note being cancelable.

	Payments Due by Period						
(in thousands)	Total	2024	2025	2026	2027	2028	Thereafter
DECD Loan	$ 1,604	$ 170	$ 335	$ 342	$ 215	$ 129	$ 413
Total	$ 1,604	$ 170	$ 335	$ 342	$ 215	$ 129	$ 413

The DECD loan is classified within Level 3 of the fair value hierarchy. The following table presents the carrying value and fair value of the DECD loan. The fair value is estimated based on the discounted cash flows using the prevailing marketing interest rates.

		December 31, 2023		December 31, 2022	
(in thousands)	Fair Value Hierarchy	Carrying Value	Fair Value	Carrying Value	Fair Value
DECD loan	Level 3	$ 1,604	$ 1,255	$ 2,729	$ 2,110

Insurance Notes

During 2023 and 2022, the Company entered into insurance promissory notes for the payment of insurance premiums at an interest rate of 7.79% and 5.48% respectively, with an aggregate principal amount outstanding of approximately $670,000 and $764,000 as of December 31, 2023 and 2022, respectively. The amount outstanding in 2023 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, 2024 and October 1, 2023, respectively.

The carrying value of the Company's insurance promissory note approximates fair value at December 31, 2023 and 2022, due to the short-term nature of the insurance note and are classified as Level 2 within the fair value hierarchy.

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 administrative offices are located in Shelton, Connecticut and Palo Alto, California.

In July 2023, the Company extended the Austin, Texas lease for an additional 37 months. The Company's renewed lease expires on February 28, 2027, with the option to extend the lease for an additional three years. Prior to the renewal, the Company's Texas lease had 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. Through June 30, 2023, 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. Beginning in the third quarter of 2023, the Company added the extended Austin, Texas lease to its balance sheet as a right-of-use asset. The Company is not reasonably certain that it will exercise the three year renewal option beginning on March 1, 2027.

In October 2015, the Company entered into a lease agreement for a facility in Trumbull, Connecticut, which was renewed in September 2020. On May 30, 2023, the Company entered into an agreement with the owner of its Trumbull, Connecticut offices to move to a more economical location in Shelton, Connecticut. The new lease in Shelton, Connecticut cancelled and replaced the Trumbull, Connecticut office lease. The new lease term is for five years, and its commencement date was October 1, 2023. Continuation of the lease would be on a month-to-month basis.

In January 2023, the Company entered into a new sublease agreement for an administrative facility in Palo Alto, California. The Company's sublease term commenced in April 2023 and expires on May 31, 2024, with no option for renewal with the sublessor.

The sublessor, Invitae, filed for bankruptcy on February 15, 2024. There will be no impact to the Company as a result of this bankruptcy filing.

The expense associated with these operating leases for the years ended December 31, 2023 and 2022 is shown in the table below (in thousands). Included in the amounts below are $58,000 and $32,000 of short term lease expenses related to rent and variable costs, respectively, for one lease during 2023 prior to its treatment as a right-of-use asset and $114,000 and $54,000 related to rent and variable costs, respectively, during 2022.

Lease Cost	Classification	Year Ended December 31, 2023	2022
Operating rent expense			
	Cost of revenue	$ 83	$ 79
	Research and development	63	27
	Sales and marketing	11	37
	General and administrative	115	66
Variable rent expense			
	Cost of revenue	$ 52	$ 39
	Research and development	14	22
	Sales and marketing	9	34
	General and administrative	74	67

Based on the Company's leases as of December 31, 2023, the table below sets forth the approximate future lease payments related to operating leases with initial terms of one year or more (in thousands).

Year	Payments
2024	$ 194
2025	167
2026	171
2027	84
2028	52
Total Operating Lease Payments	668
Less: Imputed Interest	(82)
Present Value of Lease Liabilities	586
Less: Operating Lease Liability, current portion	(159)
Operating Lease Liability, non-current portion	$ 427

Supplemental disclosure of cash flow information related to leases for the years ended December 31, 2023 and 2022 is shown in the table below (in thousands).

	Year Ended December 31, 2023	2022
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash outflows relating to operating leases	$ 459	$ 362
Weighted-average remaining lease term (in years)	3.6	3.5
Weighted-average discount rate	7.30%	9.30%

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, 2023 and 2022 totaled $324,000 and $318,000, 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 were settled as of December 31, 2022.

Business Agreements

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 2022, 15% was paid in 2023, and the remaining 17% will become payable upon completion of certain deliverables estimated to occur in the first half of 2024. During the year ended December 31, 2023, approximately $215,000 has been recorded as research and development expense in the Company's consolidated financial statement of operations for the project. During the year ended December 31, 2022, approximately $868,000, was recorded as research and development expense in the Company's consolidated financial statement of operations for the project. From the inception of the Dana-Faber, Brigham, Lodz Research Agreement through December 31, 2023, research and development expenses in the cumulative amount of $1,083,000 have been recorded. From the inception of the Dana-Faber, Brigham, Lodz Research Agreement through December 31, 2023, the Company made payments totaling $1,040,000. Additional payments of $212,000 are due to the collaboration partners in 2024 under the terms of the agreement.

On March 20, 2023, the Company entered into a licensing agreement ("Dana-Faber, Brigham, Lodz License Agreement") with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz under which the Company will license certain of its intellectual property to be used in the Company's OvaSuite product portfolio. Under the Dana-Faber, Brigham, Lodz License Agreement, the Company paid an initial license fee of $75,000, which was recorded as research and development expense on the Company's consolidated financial statement of operations, and then will pay a license maintenance fee of $50,000 on each anniversary of the date of the Dana-Faber, Brigham, Lodz License Agreement. The Dana-Faber, Brigham, Lodz License Agreement also requires non-refundable royalty payments of up to $1,350,000 based on certain regulatory approvals and commercialization milestones and further royalty payments based on the net sales of the Company's products included under the Dana-Faber, Brigham, Lodz License Agreement. No milestones have been reached as of December 31, 2023.

Contingent Liabilities

From time to time, the Company is involved in legal proceedings and regulatory proceedings arising from operations. The Company establishes reserves for specific liabilities in connection with legal actions that management deems to be probable and estimable. The Company is not currently a party to any proceeding, the adverse outcome of which would have a material adverse effect on the Company's financial position or results of operations.

NOTE 7: COMMON STOCK

Additional Shares Authorized

On February 6, 2023, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to the Company's Fourth Amended and Restated Certificate of Incorporation, as amended, to increase the authorized number of shares of the Company's common stock from 150,000,000 shares to 200,000,000 shares.

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"), 800,000 shares of the Company's common stock, par value $0.001 per share ("Common Stock") and warrants to purchase up to 799,985 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 $11.25 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 $13.20 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 Company's Warrants are classified as a long-term Warrant liability on the Company's balance sheet. The fair values of the Warrants as of December 31, 2023 and December 31, 2022 were $1,651,000 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, 2023	December 31, 2022
Dividend yield	-%	-%
Volatility	105.1 %	96.8 %
Risk-free interest rate	3.93 %	3.99 %
Expected lives (years)	3.64	4.64
Weighted average fair value	$ 2.064	$ 2.850

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.

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 expense and equity based on the percentage of the Warrant fair value of $3,984,000 and the total gross proceeds of $9,000,000. $574,000 of offering costs were allocated to the Warrants and were expensed immediately and recorded as other income (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 $751,000.

2023 At the Market Offering

On February 10, 2023, the Company entered into a Controlled Equity Offering Sales Agreement (the "Cantor Sales Agreement"), with Cantor Fitzgerald & Co. ("Cantor") as agent, pursuant to which it 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 Cantor 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 our common stock or to or through a market maker or in privately negotiated transactions. Cantor receives a Placement Fee of 3% for each completed sale of Placement Shares under the Cantor Sales Agreement.

The Company is not obligated to make any sales of the Placement Shares under the Cantor Sales Agreement. The offering of the Placement Shares pursuant to the Cantor Sales Agreement will terminate upon the earlier of (a) the sale of all of the Placement Shares subject to the Cantor Sales Agreement or (b) the termination of the Cantor Sales Agreement by Cantor or the Company, as permitted therein. As of December 31, 2023, and December 31, 2022, the Company had $0 and $150,000, respectively, of deferred transaction-related offering costs recorded in other assets in the Company's consolidated balance sheet. $7,000 was recorded as an offset to additional paid-in-capital representing transaction-related offering costs related to the Cantor Sales Agreement. The remaining $143,000 was recorded as general and administrative expense on the Company's consolidated financial statement of operations.

During the year ended December 31, 2023, the Company sold 35,552 shares of the Placement Shares, for gross proceeds of approximately $211,000. For the year ended December 31, 2023, the Company recorded $134,000 as an offset to additional paid-in capital representing transaction-related offering costs of the Placement Shares.

In connection with a follow-on equity offering on July 24, 2023, the Company delivered written notice to Cantor on July 19, 2023 that it was suspending the prospectus supplement, dated February 10, 2023, related to the Company's common stock issuable under the Cantor Sales Agreement. The Company will not make any sales of common stock pursuant to the Cantor Sales Agreement unless and until a new prospectus supplement is filed with the SEC. The Cantor Sales Agreement remains in full force and effect during the suspension.

2023 Equity Line of Credit

On March 28, 2023, the Company entered into a purchase agreement (the "LPC Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") and a registration rights agreement (the "LPC Registration Rights Agreement"), pursuant to which the Company has the right, in its sole discretion, to sell to Lincoln Park shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), having an aggregate value of up to $10,000,000 (the "Purchase Shares"), subject to certain limitations and conditions set forth in the LPC Purchase Agreement. The Company will control the timing and amount of any sales of Purchase Shares to Lincoln Park pursuant to the LPC Purchase Agreement.

Under the LPC Purchase Agreement, on any business day after March 28, 2023 selected by the Company over the 36-month term of the LPC Purchase Agreement (each, a "Purchase Date"), the Company may direct Lincoln Park to purchase up to 6,667 shares of Common Stock on such Purchase Date (a "Regular Purchase"); provided, however, that (i) a Regular Purchase may be increased to up to 13,333 shares, if the closing sale price per share of the Common Stock on The Nasdaq Capital Market is not below $7.50 on the applicable Purchase Date; (ii) a Regular Purchase may be increased to up to 16,666 shares, if the closing sale price per share of the Common Stock on The Nasdaq Capital Market is not below $11.25 on the applicable Purchase Date; and (iii) a Regular Purchase may be increased to up to 20,000 shares, if the closing sale price per share of the Common Stock on The Nasdaq Capital Market is not below $15.00 on the applicable Purchase Date. All terms of the LPC Purchase Agreement have been adjusted for the Reverse Stock Split. In any case, Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $1,000,000. The above-referenced share amount limitations and closing sale price thresholds are subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the LPC Purchase Agreement. The purchase price per share for each such Regular Purchase will be equal to the lesser of:

1. the lowest sale price for the Common Stock on The Nasdaq Capital Market on the date of sale; and
2. the average of the three lowest closing sale prices for the Common Stock on The Nasdaq Capital Market during the 10 consecutive business days ending on the business day immediately preceding the purchase date.

The Company also has the right to direct Lincoln Park, on any business day on which the Company has properly submitted a Regular Purchase notice for the maximum amount the Company is then permitted to sell to Lincoln Park in such Regular Purchase, to purchase an additional amount of the Common Stock (an "Accelerated Purchase") of additional shares based on criteria established in the LPC Purchase Agreement. An Accelerated Purchase, which is at the Company's sole discretion, may be subject to additional requirements and discounts if certain conditions are met as defined in the LPC Purchase Agreement.

During the year ended December 31, 2023, the Company sold 360,943 shares under the LPC Purchase Agreement for gross proceeds of approximately $1,177,000. The Company incurred approximately $329,000 of costs related to the execution of the LPC Purchase Agreement, all of which are reflected in the Company's consolidated financial statements. Of the total costs incurred, approximately $258,000 was paid in common stock to Lincoln Park for a commitment fee and $30,000 was paid for Lincoln Park expenses. These transaction costs were included in other expense in the Company's statement of operations. Approximately $41,000 was incurred for legal fees during the year ended December 31, 2023 and were included in general and administrative expenses on the Company's statement of operations.

2023 Registered Direct Offering

On July 20, 2023, the Company entered into a securities purchase agreement (the "2023 Direct Offering Agreement"), with several investors relating to the issuance and sale of 1,694,820 shares of its common stock, par value $0.001 per share (the "2023 Direct Offering").

Pursuant to the 2023 Direct Offering Agreement, the Company issued 1,650,473 shares of common stock to certain investors at an offering price of $2.75 per share, and 44,347 shares of common stock to its directors and executive officers at an offering price of $3.98 per share, which was the consolidated closing bid price of the Company's common stock on The Nasdaq Capital Market on July 19, 2023. The aggregate gross proceeds to the Company from the 2023 Direct Offering were approximately $4.7 million, before deducting placement agent fees and other estimated expenses of $597,000 payable by the Company.

The Company engaged Alliance Global Partners ("AGP") to act as sole placement agent in the 2023 Direct Offering. The Company paid the placement agent a cash fee equal to 7.0% of the aggregate gross proceeds generated from the 2023 Direct Offering, except that, with respect to proceeds from the sale of 182,447 shares of common stock to certain investors, including directors and executive officers of the Company, the placement agent's cash fee was 3.5%. The Company also

reimbursed the placement agent for its accountable offering-related legal expenses of $75,000 and a non-accountable expense allowance of $30,000.

Warrants

Warrants outstanding as of December 31, 2023 and 2022 were as follows:

		Exercise Price	Number of Shares Outstanding under Warrant	
Issuance Date	**Expiration Date**	**per Share**	**December 31, 2023**	**December 31, 2022**
August 25, 2022	August 25, 2027	$ 13.20	799,985	799,985
			799,985	799,985

As discussed in Note 12, effective upon the closing of a follow-on equity offering, the Company also amended certain of the existing warrants to purchase up to an aggregate of 366,664 shares at an exercise price of $13.20 per share and a termination date of August 25, 2027, so that the amended warrants will have a reduced exercise price of $4.13 per share and a new termination date of January 26, 2029. The other terms of the amended warrants will remain unchanged.

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, 2023 and 2022 was as follows:

	Year Ended December 31,	
	2023	**2022**
Numerator:		
Net Loss	$ (16,690)	$ (29,885)
Denominator:		
Shares used in computing net loss per share, basic and diluted	9,233,306	7,769,109
Net loss per share, basic and diluted	$ (1.81)	$ (3.85)

Due to net losses for the years ended December 31, 2023 and 2022, 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, 2023 and 2022 were as follows:

	Year Ended December 31,	
	2023	**2022**
Stock options	759,922	655,139
Restricted stock units	59,463	-
Warrants	799,985	799,985
Potential common shares	1,619,370	1,455,124

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, 2023, there were no shares of Aspira common stock available for future grants under the 2010 Plan.

As of December 31, 2023, a total of 245,154 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 699,485. In May 2023, the Company's stockholders approved an increase of 333,333 to the number of shares available for issuance under the 2019 Plan for a total of 1,032,818. 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, 2023, there were 165,861 shares of Aspira common stock available for future grants under the 2019 Plan.

As of December 31, 2023, there were 514,768 shares of Aspira common stock subject to outstanding stock options and there were 59,463 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, 2023 and 2022 was as follows:

	2010 Stock Option Plan	2019 Stock Option Plan	Total
Shares available at December 31, 2021	-	248,613	248,613
Options forfeited	2,650	198,625	201,275
Options granted	-	(174,175)	(174,175)
Restricted stock units forfeited	-	346	346
Restricted stock units granted	-	(29,223)	(29,223)
Shares expired	(2,650)	(5,754)	(8,404)
Shares available at December 31, 2022	-	238,432	238,432
Shares added to the plan	-	333,333	333,333
Options forfeited	41,950	250,859	292,809
Options granted	-	(397,503)	(397,503)
Restricted stock units forfeited	-	-	-
Restricted stock units granted	-	(259,161)	(259,161)
Shares expired	(41,950)	(99)	(42,049)
Shares available at December 31, 2023	-	165,861	165,861

The stock option activity under the 2010 Plan and the 2019 Plan for the years ended December 31, 2023 and 2022 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Options outstanding at December 31, 2021	683,861	$ 44.40	$ 3,797,181	7.44
Granted	174,175	14.17		
Exercised	(1,533)	8.13		
Forfeited	(201,275)	68.12		
Options outstanding at December 31, 2022	655,228	$ 29.25	$ -	6.06
Granted	397,503	6.57		
Exercised	-	-		
Forfeited	(292,809)	28.90		
Options outstanding at December 31, 2023	759,922	$ 17.48	$ 113,929	5.37
Shares exercisable:				
December 31, 2023	452,606	$ 22.57	$ 33,073	3.03
Shares expected to vest:				
December 31, 2023	201,328	$ 10.31	$ 41,992	8.45

The total intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was $0 and $5,000 respectively.

The total fair value of vested options as of December 31, 2023 and 2022 was $6,073,000 and $5,982,000, respectively.

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, 2023 and 2022 were as follows:

	December 31, 2023	December 31, 2022
Dividend yield	- %	- %
Volatility	138.3 %	92.7 %
Risk-free interest rate	4.45 %	2.45 %
Expected lives (years)	2.00	2.00
Weighted average fair value	$ 4.160	$ 7.350

The non-cash stock-based compensation expense included in cost of revenue and operating expenses by functional area for the years ended December 31, 2023 and 2022 was as follows:

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Cost of revenue	$ 33	$ 76
Research and development	325	177
Sales and marketing	47	354
General and administrative	1,319	1,807
Total	$ 1,724	$ 2,414

As of December 31, 2023, total unrecognized compensation cost related to unvested stock option awards was approximately $677,000, and the related weighted average period over which it is expected to be recognized was 1.81 years. As of December 31, 2023, there was $104,000 in unrecognized compensation costs related to restricted stock units, and the related weighted average period over which it is expected to be recognized is 0.50 years.

401(k) Plan

The Company's 401(k) Plan allows eligible employees to defer up to an annual limit of the lesser of 90.0% of eligible compensation or a maximum contribution amount subject to the Internal Revenue Service annual contribution limit. The Company is not required to make Company contributions under the 401(k) Plan. During the years ended December 31, 2023 and 2022, 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, 2023 or 2022 because of net losses during those years. These net losses were generated from domestic operations. Loss from continuing operations before income taxes for the years ended December 31, 2023 and 2022 were $16.7 million and $29.9 million, 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, 2023 and 2022. Therefore, there was no deferred income tax expense or benefit for the years ended December 31, 2023 or 2022. There is no portion of the valuation allowance for deferred tax assets for which subsequently recognized tax benefits will be credited directly to contributed capital.

The components of net deferred tax assets (liabilities) at December 31, 2023 and 2022 were as follows:

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Deferred tax assets:		
Net operating losses	$ 52,540	$ 44,509
Capitalized research expenses	3,432	3,686
Fixed asset depreciation	487	678
Other	697	804
ASC 842 Right of Use Liability	137	-
Total deferred tax assets	57,293	49,677
Valuation allowance	(57,170)	(49,677)
Deferred tax assets	$ 123	$ -
Deferred tax liabilities:		
ASC 842 Right of Use Asset	$ (123)	$ -
Deferred tax liabilities	$ (123)	$ -
Net deferred tax asset	$ -	$ -

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2023 and 2022 was as follows:

	Year Ended December 31,	
	2023	2022
Tax at federal statutory rate	21 %	21 %
State tax, net of federal benefit	-	5
Change in valuation allowance	(17)	(26)
Change in warrant valuation	1	1
Net operating loss reduction due to Section 382 limitation	(1)	-
Permanent items	(1)	(1)
Deferred Adjustments, Return to Provision	(3)	-
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.

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 2024 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 of approximately $31 million 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 $116 million arising on or after January 1, 2018, can generally be carried forward indefinitely but such federal NOL carryforwards are permitted to be used in any table year to offset up to 80% of future taxable income annually. State NOLs will expire in varying amounts from 2024 through 2043 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 portions of the Company's NOLs could expire before the Company generates sufficient taxable income.

The valuation allowance was $57.2 million and $49.7 million at December 31, 2023 and 2022, respectively. The increase of approximately $7.5 million between 2022 and 2023 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, 2023, the Company's federal returns for the years ended 2020 through the current period and most state returns for the years ended 2019 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 2020 and 2019, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2022 reflect research and development carryforwards of $4.4 million and $5.9 million, respectively. For the year ended December 31, 2023, the Company anticipates claiming additional research and development credits of $0.3 million on its federal tax return and $0.2 million on its California tax return.

As of December 31, 2023, the Company's gross unrecognized tax benefits are approximately $10.7 million 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, 2021	$ 4,937	$ 5,644	$ 10,581
Return to provision true up	-	-	-
Increase in tax position during 2022	223	212	435
Decrease due to expirations during 2022	(785)	-	(785)
Balance at December 31, 2022	$ 4,375	$ 5,856	$ 10,231
Return to provision true up	-	-	-
Increase in tax position during 2023	282	211	493
Decrease due to expirations during 2023	-	-	-
Balance at December 31, 2023	$ 4,657	$ 6,067	$ 10,724

The increase for the year ended December 31, 2023 is related to positions taken in that year. If the $10.7 million of unrecognized income tax benefit is recognized, approximately $10.7 million would impact the effective tax rate in the period in which each of the benefits is recognized.

The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. The Company recognizes interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations and comprehensive loss. The Company has not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2023 and 2022. Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

NOTE 11: RELATED PARTY TRANSACTIONS

None.

NOTE 12: SUBSEQUENT EVENTS

On January 24, 2024, the Company entered into a securities purchase agreement (the “2024 Direct Offering Agreement”), with several investors relating to the issuance and sale of 1,371,000 shares of its common stock, par value $0.001 per share, and pre-funded warrants to purchase 200,000 shares of Common Stock (the “Pre-Funded Warrants”), in a registered direct offering, together with accompanying warrants to purchase 1,571,000 shares of Common Stock (the “Purchase Warrants”, and together with the Pre-Funded Warrants, the “Warrants”) in a concurrent private placement (the “Concurrent Private Offering” and together with the registered direct offering, the “2024 Direct Offering”).

Pursuant to the 2024 Direct Offering Agreement, the Company issued 1,368,600 shares of common stock to certain investors at an offering price of $3.50 per share, and 2,400 shares of common stock to its Chief Executive Officer, Nicole Sandford, at an offering price of $4.2555 per share, which was the consolidated closing bid price of our common stock on The Nasdaq Capital Market on January 24, 2024 of $4.13 per share plus $0.125 per Purchase Warrant. The purchase price of each Pre-Funded Warrant is equal to the combined purchase price at which a share of Common Stock and the accompanying Purchase Warrant is sold in this 2024 Direct Offering, minus $0.0001. The gross proceeds to the Company from the 2024 Direct Offering were approximately $5.5 million, before deducting placement agent fees and other estimated expenses of $941,000 payable by the Company. The 2024 Direct Offering closed on January 26, 2024.

The Pre-Funded Warrants will be exercisable at any time after the date of issuance and will have an exercise price of $0.0001 per share. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage to a percentage not in excess of 9.99% by providing at least 61 days’ prior notice to the Company.

The Purchase Warrants will have an exercise price of $4.13 per share and will be exercisable beginning six months after issuance and will expire 5 years from the initial exercise date.

The Company engaged AGP to act as sole placement agent in the 2024 Direct Offering. The Company paid the placement agent a cash fee equal to 7.0% of the aggregate gross proceeds generated from the 2024 Direct Offering, except that, with respect to proceeds raised in this 2024 Direct Offering from certain designated persons, AGP's cash fee is reduced to 3.5% of such proceeds, and to reimburse certain fees and expenses of the placement agent in connection with the 2024 Direct Offering. The Company also reimbursed the placement agent for its accountable offering-related legal expenses of $75,000 and a non-accountable expense allowance of $30,000.

Effective upon the closing of the 2024 Direct Offering, the Company also amended certain existing warrants to purchase up to an aggregate of 366,664 shares at an exercise price of $13.20 per share and a termination date of August 25, 2027, so that the amended warrants will have a reduced exercise price of $4.13 per share and a new termination date of January 26, 2029. The other terms of the amended warrants will remain unchanged.

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 29, 2024

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

Date: March 29, 2024

/s/ Torsten Hombeck
Torsten Hombeck
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

POWER OF ATTORNEY

Each of the undersigned officers and directors of Aspira Women's Health Inc., hereby constitutes and appoints Nicole Sandford and Torsten Hombeck, and each or any of them, as their true and lawful attorney-in-fact and agent, for them and in their name, place and stead, in any and all capacities, to sign their name to any and all amendments to this Report on Form 10-K, and other related documents, and to cause the same to be filed with the Securities and Exchange Commission, granting unto said attorneys, full power and authority to do and perform any act and thing necessary and proper to be done in the premises, as fully to all intents and purposes as the undersigned could do if personally present, and the undersigned for himself hereby ratifies and confirms all that said attorney shall lawfully do or cause to be done by virtue hereof.

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

Name	**Title**	**Date**
/s/ Nicole Sandford Nicole Sandford	President and Chief Executive Officer (Principal Executive Officer) and Director	March 29 2024
/s/ Torsten Hombeck Torsten Hombeck	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29 2024
/s/ Jannie Herchuk Jannie Herchuk	Chair of the Board of Directors	March 29 2024
/s/ Stefanie Cavanaugh Stefanie Cavanaugh	Director	March 29 2024
/s/ Celeste Fralick Celeste Fralick	Director	March 29 2024
/s/ Ellen O'Connor-Vos Ellen O'Connor-Vos	Director	March 29 2024
/s/ Winfred Parnell Winfred Parnell	Director	March 29 2024