

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended March 31, 2022**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number: 001-34810**

**Aspira Women's Health Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**12117 Bee Caves Road, Building Three, Suite 100,  
Austin, Texas**

(Address of principal executive offices)

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

**33-0595156**

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

**78738**

(Zip Code)

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

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

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 ☐

Non-accelerated filer ☒

Accelerated filer ☐

Smaller reporting company ☒

Emerging growth company ☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of May 6, 2022, the registrant had 112,209,064 shares of common stock, par value \$0.001 per share, outstanding.

# ASPIRA WOMEN'S HEALTH INC.

## FORM 10-Q

For the Quarter Ended March 31, 2022

### Table of Contents

	<b>Page</b>
<b>PART I</b> Financial Information	<u>3</u>
Item 1 Financial Statements	<u>3</u>
Condensed Consolidated Balance Sheets as of March 31, 2022 (unaudited) and December 31, 2021	<u>3</u>
Condensed Consolidated Statements of Operations for the three months ended March 31, 2022 and 2021 (unaudited)	<u>4</u>
Condensed Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2022 and 2021 (unaudited)	<u>5</u>
Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2022 and 2021 (unaudited)	<u>6</u>
Notes to Condensed Consolidated Financial Statements (unaudited)	<u>7</u>
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>14</u>
Item 3 Quantitative and Qualitative Disclosures About Market Risk	<u>26</u>
Item 4 Controls and Procedures	<u>26</u>
<b>PART II</b> Other Information	<u>26</u>
Item 1 Legal Proceedings	<u>26</u>
Item 1A Risk Factors	<u>27</u>
Item 6 Exhibits	<u>28</u>
<b>SIGNATURES</b>	<u>29</u>

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

## PART I - FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

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

	<b>March 31, 2022</b>	<b>December 31, 2021</b>
<b>Assets</b>	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 26,855	\$ 37,180
Accounts receivable	1,136	1,027
Prepaid expenses and other current assets	1,620	1,624
Inventories	189	174
Total current assets	29,800	40,005
Property and equipment, net	480	464
Right-of-use assets	331	346
Restricted cash	250	250
Other assets	-	14
Total assets	<u>\$ 30,861</u>	<u>\$ 41,079</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,298	\$ 1,501
Accrued liabilities	4,035	5,299
Current portion of long-term debt	223	201
Short-term debt	519	779
Lease liability	64	60
Total current liabilities	6,139	7,840
Non-current liabilities:		
Long-term debt	2,646	2,718
Lease liability	332	349
Total liabilities	9,117	10,907
Commitments and contingencies (Note 2)		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 150,000,000 shares authorized at March 31, 2022 and December 31, 2021; 112,141,741 and 112,138,741 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	112	112
Additional paid-in capital	502,628	501,788
Accumulated deficit	(480,996)	(471,728)
Total stockholders' equity	21,744	30,172
Total liabilities and stockholders' equity	<u>\$ 30,861</u>	<u>\$ 41,079</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenue:		
Product	\$ 1,835	\$ 1,416
Genetics	58	80
Total revenue	1,893	1,496
Cost of revenue <sup>(1)</sup> :		
Product	857	655
Genetics	75	238
Total cost of revenue	932	893
Gross profit	961	603
Operating expenses:		
Research and development <sup>(2)</sup>	1,348	872
Sales and marketing <sup>(3)</sup>	4,497	3,108
General and administrative <sup>(4)</sup>	4,363	2,509
Total operating expenses	10,208	6,489
Loss from operations	(9,247)	(5,886)
Interest expense, net	(18)	(24)
Other expense, net	(3)	(10)
Net loss	\$ (9,268)	\$ (5,920)
Net loss per share - basic and diluted	\$ (0.08)	\$ (0.05)
Weighted average common shares used to compute basic and diluted net loss per common share	112,139,038	108,661,712
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:		
(1) Cost of revenue	\$ 52	\$ 34
(2) Research and development	(4)	26
(3) Sales and marketing	147	139
(4) General and administrative	643	290

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-In Capital</b>	<b>Deficit</b>	<b>Stockholders' Equity</b>
<b>Balance at December 31, 2021</b>	112,138,741	\$ 112	\$ 501,788	\$ (471,728)	\$ 30,172
Net loss	-	-	-	(9,268)	(9,268)
Common stock issued in conjunction with exercise of stock options	3,000	-	2	-	2
Stock-based compensation expense	-	-	838	-	838
<b>Balance at March 31, 2022</b>	<u>112,141,741</u>	<u>\$ 112</u>	<u>\$ 502,628</u>	<u>\$ (480,996)</u>	<u>\$ 21,744</u>

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-In Capital</b>	<b>Deficit</b>	<b>Stockholders' Equity</b>
<b>Balance at December 31, 2020</b>	104,619,876	\$ 105	\$ 449,680	\$ (440,066)	\$ 9,719
Net loss	-	-	-	(5,920)	(5,920)
Common stock issued in conjunction with exercise of stock options	196,976	-	317	-	317
Common stock issued in conjunction with public offering, net of issuance costs	6,900,000	7	47,713	-	47,720
Stock-based compensation expense	-	-	489	-	489
<b>Balance at March 31, 2021</b>	<u>111,716,852</u>	<u>\$ 112</u>	<u>\$ 498,199</u>	<u>\$ (445,986)</u>	<u>\$ 52,325</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,268)	\$ (5,920)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	2	16
Depreciation and amortization	64	90
Stock-based compensation expense	838	489
Loss on sale and disposal of property and equipment	2	1
Changes in operating assets and liabilities:		
Accounts receivable	(109)	(87)
Prepaid expenses and other assets	18	(94)
Inventories	(15)	(41)
Accounts payable, accrued liabilities and other liabilities	(1,705)	291
Net cash used in operating activities	(10,173)	(5,255)
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(82)	(41)
Net cash used in investing activities	(82)	(41)
<b>Cash flows from financing activities:</b>		
Principal repayment of DECD loan	(72)	(3)
Proceeds from issuance of common stock from exercise of stock options	2	317
Proceeds from public offering	-	48,236
Payment of offering costs for public offering	-	(516)
Net cash (used in) provided by financing activities	(70)	48,034
Net (decrease) increase in cash, cash equivalents and restricted cash	(10,325)	42,738
Cash, cash equivalents and restricted cash, beginning of period	37,430	16,631
Cash, cash equivalents and restricted cash, end of period	\$ 27,105	\$ 59,369
<b>Reconciliation to Consolidated Balance Sheet:</b>		
Cash and cash equivalents	\$ 26,855	\$ 59,369
Restricted cash	250	-
Unrestricted and restricted cash and cash equivalents	\$ 27,105	\$ 59,369
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for interest	20	29
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Net decrease in right-of-use assets	(15)	(15)

See accompanying notes to the unaudited condensed consolidated financial statements.

**Aspira Women's Health Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
(Unaudited)

**1. ORGANIZATION, BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING AND REPORTING POLICIES**

***Organization***

Aspira Women's Health Inc., formerly known as Vermillion, Inc. ("Aspira" and its wholly-owned subsidiaries are collectively referred to as the "Company") is incorporated in the state of Delaware, and is engaged in the business of developing and commercializing diagnostic tests for gynecologic disease. The Company currently markets and sells the following products and related services: (1) OVA1, a blood test intended as an aid to further assess the likelihood of malignancy in women with an ovarian adnexal mass for which surgery is planned when the physician's independent clinical and radiological evaluation does not indicate malignancy; (2) OVERA, a second-generation biomarker reflex intended to maintain OVA1's high sensitivity while improving specificity; (3) OVA1plus, a reflex offering which uses OVA1 as the primary test and OVERA as a confirmation for OVA1 intermediate range results and leverages the strengths of OVA1's Multivariate Index Assay ("MIA") sensitivity and OVERA's (MIA2G) specificity and as a result reduces false elevations by over 40%; (4) Aspira GenetiX, a genetic test for hereditary gynecologic cancer risk, with a core focus on hereditary female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers; and (5) Aspira Synergy, the Company's decentralized testing platform and cloud service for decentralized global access of both protein biomarker and hereditary genetic testing. The Company plans to make OVA1, OVERA, OVA1plus and Aspira GenetiX and future technology available through Aspira Synergy. The Company's 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. The Company's OVERA test, which includes an updated version of OVACALC, received FDA 510(k) clearance in March 2016. OVA1 and OVERA each use the Roche cobas 4000, 6000 and 8000 platforms for analysis of proteins. Through March 31, 2022, the Company's product and related services revenue has been limited to revenue generated by sales of OVA1, OVA1plus and Aspira GenetiX. In 2021, the Company entered into decentralized arrangements with large healthcare networks and large practices for its Aspira Synergy platform offering specialty and genetic testing solutions. The modules available under Aspira Synergy include the Company's flagship OVA1plus risk assessment, Genetics Carrier Screening, and Genetics Hereditary Cancer solutions. The Company has entered into four technology transfer agreements since the launch of Aspira Synergy. The first two agreements are with two of the nation's largest and leading independent women's healthcare groups which together include approximately 750 providers and serve approximately 950,000 patients annually. The other two agreements are with independent laboratories providing services across five states. In the fourth quarter of 2021, the Company started receiving specimens for accessioning related to its OVA1 Aspira Synergy product.

***Liquidity***

As of March 31, 2022, the Company had \$26,855,000 of cash and cash equivalents (excluding restricted cash of \$250,000), an accumulated deficit of approximately (\$480,996,000), and working capital of \$23,661,000. For the three months ended March 31, 2022, the Company incurred a net loss of (\$9,268,000) and used cash in operations of (\$10,173,000). The Company has incurred significant net losses and negative cash flows from operations since inception and the Company also expects to continue to incur a net loss and negative cash flows from operations for 2022. There can be no assurance that the Company will achieve or sustain profitability or positive cash flow from operations. The Company's management believes that the Company's cash and cash equivalents will be sufficient to fund its operations for the next twelve months from the issuance of the condensed consolidated financial statements. These condensed consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern.

While the Company believes that it has sufficient capital to fund its operations for the next twelve months, the Company is currently evaluating its capital needs beyond the next twelve months which may involve additional capital raises and/or other financing activities in order to continue to fund operations at current cash expenditure

levels. The Company may take further action to protect its liquidity position, including in the event that the Company's existing cash on hand is not sufficient to fund its operations, meet its capital requirements or satisfy its anticipated obligations as they become due. Such actions may include, but are not limited to:

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

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. The novel coronavirus has since spread to over 100 countries, including every state in the United States. In March 2020, the World Health Organization declared COVID-19, the disease caused by the novel coronavirus, a pandemic, and the United States declared a national emergency with respect to the coronavirus outbreak. This outbreak has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. In order to reduce the impact of limitations on visiting physician offices due to closures and quarantines, the Company implemented other mechanisms for reaching physicians such as virtual sales representative meetings, Key Opinion Leader presentations, and increased digital sales and marketing. Patient enrollment for our planned clinical research studies has been slower than originally planned due to the impact of clinic closures and patients not seeking medical care in some states, which has led to delays in the completion of such studies. Given the uncertainties of the resurgence of the COVID-19 pandemic, the Company is unable to estimate the extent of the impact of the COVID-19 pandemic on its operations or liquidity.

### ***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management of the Company, all adjustments, consisting of normal recurring adjustments necessary for the fair statement of results for the periods presented, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim unaudited condensed consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. The condensed consolidated balance sheet at December 31, 2021 included in this report has been derived from the audited consolidated financial statements at that date but does not include all the information and notes required by GAAP. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2021 included in Aspira's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 31, 2022.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimated results.



## **Significant Accounting Policies**

### **Revenue Recognition**

*Product Revenue* – OVA1, OVERA and OVA1plus: The Company recognizes product revenue in accordance with the provisions of ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”). Product revenue is recognized upon completion of the OVA1, OVERA or OVA1plus test and delivery of results to the physician based on estimates of amounts that will ultimately be realized. In determining the amount of revenue to be recognized for a delivered test result, the Company considers factors such as payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and the Company, and any developments or changes that could impact reimbursement. These estimates require significant judgment by management as the collection cycle on some accounts can be as long as one year. The effect of any change made to an estimated input component and, therefore revenue recognized, would be recorded as a change in estimate at the time of the change.

The Company also reviews its patient account population and determines an appropriate distribution of patient accounts by payer (i.e., Medicare, patient pay, other third-party payer, etc.) into portfolios with similar collection experience. The Company has elected this practical expedient that, when evaluated for collectability, results in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on an individual contract basis. During the period ended March 31, 2022, there were no adjustments to estimates of variable consideration to derecognize revenue for services provided in a prior period. There were no impairment losses on accounts receivable recorded during the periods ended March 31, 2022 and 2021.

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

### **Recent Accounting Pronouncements**

In June 2016, the Financial Accounting Standards Board issued Accounting Standard Update No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). This update changes the impairment model from the currently used incurred loss methodology to an expected loss methodology, which will result in the more timely recognition of losses. This ASU 2016-13 is scheduled to be effective in 2023 for smaller reporting companies. The Company is in the process of evaluating the impact of this standard on its consolidated financial statements.

## **2. COMMITMENTS AND CONTINGENCIES**

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

On May 1, 2020, the Company obtained the Paycheck Protection Program loan (the “PPP Loan”) from BBVA USA in the aggregate amount of approximately \$1,006,000. The Company applied for forgiveness of the PPP Loan in March 2021, and, effective May 27, 2021, the U.S. Small Business Administration confirmed the waiver of the Company’s repayment of the PPP Loan which was recognized as a gain in other income in 2021. The Company remains subject to an audit of the PPP loan. There is no assurance that the Company will not be required to repay all or a portion of the PPP Loan, as a result of any such audit.

## Loan Agreement

On March 22, 2016, the Company entered into a loan agreement (as amended, the "DECD Loan Agreement") with the State of Connecticut Department of Economic and Community Development (the "DECD"), pursuant to which the Company may borrow up to \$4,000,000 from the DECD. The loan bears interest at a fixed rate of 2.0% per annum and requires equal monthly payments of principal and interest until maturity, which occurs on April 15, 2026. As security for the loan, the Company has granted the DECD a blanket security interest in the Company's personal and intellectual property. The DECD's security interest in the Company's intellectual property may be subordinated to a qualified institutional lender.

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

Under the terms of the DECD Loan Agreement, the Company may be eligible for forgiveness of up to \$1,500,000 of the principal amount of the loan if the Company achieves certain job creation and retention milestones by December 31, 2022. Conversely, if the Company is either unable to retain 25 full-time employees with a specified average annual salary for a consecutive two-year period or does not maintain the Company's Connecticut operations through March 22, 2026, the DECD may require early repayment of a portion or all of the loan plus a penalty of 5% of the total funded loan.

Long-term debt consisted of the following:

(in thousands)	March 31,	
	2022	2021
DECD loan, net of issuance costs	\$ 2,869	\$ 2,919
Less: Current portion, net of issuance costs	(223)	(201)
Total long-term debt, net of issuance costs	<u>\$ 2,646</u>	<u>\$ 2,718</u>

As of March 31, 2022, the annual amounts of future minimum principal payments due under the Company's contractual obligation are shown in the table below. Unamortized debt issuance costs for the DECD loan were \$14,000. Debt related to the insurance promissory note of \$519,000, as described below, is not included in the following table due to the insurance promissory note being cancelable.

(in thousands)	Payments Due by Period						
	Total	2022	2023	2024	2025	2026	Thereafter
DECD Loan	\$ 2,883	\$ 154	\$ 406	\$ 452	\$ 461	\$ 341	\$ 1,069
Total	<u>\$ 2,883</u>	<u>\$ 154</u>	<u>\$ 406</u>	<u>\$ 452</u>	<u>\$ 461</u>	<u>\$ 341</u>	<u>\$ 1,069</u>

## Insurance Notes

During 2021, the Company entered into an insurance promissory note for the payment of insurance premiums at an interest rate of 3.74%, with an aggregate principal amount outstanding of approximately \$519,000 and \$779,000 as of March 31, 2022 and December 31, 2021, respectively. This note is payable in ten monthly installments with a maturity date of October 1, 2022 and has no financial or operational covenants.

## 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 Clinical Laboratory Improvements Amendments of 1988 ("CLIA") laboratory used by Aspira Labs, Inc., is located in Austin, Texas, and the CLIA laboratory used for research and development services is located in Trumbull, Connecticut. In October 2021, the Company renewed the Austin, Texas lease for one additional year. The Company's renewed lease expires on January 31, 2023, with no automatic renewal or renewal option. The Company's Texas lease has a term of 12 months. The Company recognized the lease payments in profit and loss on a straight-line basis over the term of the lease, and variable lease payments in the period in which the obligation for the payments was incurred.

In October 2015, the Company entered into a lease agreement for a facility in Trumbull, Connecticut. The lease required initial payments for the buildout of leasehold improvements to the office space, which were approximately \$596,000. In September 2020, the Company exercised the renewal option for its Trumbull, Connecticut lease. The Company's renewed lease expires on June 30, 2026, with a five year renewal option. The Company is not reasonably certain that it will exercise the five year renewal option beginning on July 1, 2026.

The expense associated with these operating leases for the three months ended March 31, 2022 and 2021 is shown in the table below (in thousands).

Lease Cost	Classification	Three Months Ended March 31,	
		2022	2021
Operating rent expense			
	Cost of revenue	\$ 20	\$ 13
	Research and development	7	9
	Sales and marketing	9	11
	General and administrative	16	18
Variable rent expense			
	Cost of revenue	\$ 10	\$ 7
	Research and development	6	4
	Sales and marketing	9	12
	General and administrative	18	16

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

	2022	\$ 73
	2023	106
	2024	116
	2025	123
	2026	64
	Total Operating Lease Payments	482
	Less: Interest	(86)
	Present Value of Lease Liabilities	\$ 396

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

Weighted-average remaining lease term (in years)	4.2
Weighted-average discount rate	9.33%

### ***Non-cancelable Royalty Obligations***

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 three months ended March 31, 2022 and 2021 totaled \$73,000 and \$57,000, respectively, as recorded in cost of revenue in the condensed consolidated statements of operations.

### ***Commercial Reorganization***

During the three months ended March 31, 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 condensed 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, of which \$162,000 has been received during the three months ended March 31, 2022 and \$361,000 is included in Prepaid expenses and other current assets on the condensed consolidated balance sheet as of March 31, 2022. As of March 31, 2022, remaining unpaid estimated charges in the amount of \$508,000 are included in Accrued liabilities on the condensed consolidated balance sheet and are expected to be paid within the next 12 months.

### ***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.

## **3. STOCKHOLDERS' EQUITY**

### ***2021 Public Offering***

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

Under the 2021 Underwriting Agreement, the Company granted the 2021 Underwriters an option to purchase up to an additional 900,000 shares of Aspira common stock at the public offering price, less the underwriting discount of \$0.4875 per share. On February 5, 2021, the 2021 Underwriters notified the Company that they were exercising this option in connection with the closing of the 2021 Offering. The 2021 Offering, including the additional 900,000 shares of Aspira common stock, closed on February 8, 2021 and resulted in net proceeds to the Company of approximately \$47,720,000, after deducting underwriting discounts and offering expenses of \$516,000. There was a change in estimate in the third quarter of 2021 in the amount of \$138,000 relating to an expense reversal of offering costs.

### ***2019 Stock Incentive Plan***

At the Company's 2019 annual meeting of stockholders, the Company's stockholders approved the Vermillion, Inc. 2019 Stock Incentive Plan (the "2019 Plan"). The purposes of the 2019 Plan are (i) to align the interests of the Company's stockholders and recipients of awards under the 2019 Plan by increasing the proprietary interest of such recipients in the Company's growth and success; (ii) to advance the interests of the Company by attracting and retaining non-employee directors, officers, other employees, consultants, independent

contractors and agents; and (iii) to motivate such persons to act in the long-term best interests of the Company and its stockholders. The 2019 Plan allows the Company to grant stock options, stock appreciation rights, restricted stock, restricted stock units and performance awards to participants.

Subject to the terms and conditions of the 2019 Plan, the initial number of shares authorized for grants under the 2019 Plan is 10,492,283. To the extent an equity award granted under the 2019 Plan expires or otherwise terminates without having been exercised or paid in full, or is settled in cash, the shares of common stock subject to such award will become available for future grant under the 2019 Plan. As of March 31, 2022, 11,119,308 shares of Aspira common stock were subject to outstanding stock options, and 269,297 shares of Aspira common stock were subject to unvested restricted stock awards and a total of 2,589,507 shares of Aspira common stock were reserved for issuance under the 2019 Plan.

### **Stock-Based Compensation**

During the three months ended March 31, 2022, the Company granted the following awards under the 2019 Plan. In addition, assumptions included in the fair value per share calculations were expected terms of one to four years, one to five year treasury interest rates of 1.38% to 2.28% and market close prices ranging from \$1.04 to \$1.08. The Company recorded \$334,000 in forfeitures for the three months ended March 31, 2022.

<b>Grant Date</b>	<b>Number of Shares</b>	<b>Type of Award</b>	<b>Exercise Price / Share</b>	<b>Fair Value / Share</b>
1/28/2022	222,000	Options	\$ 1.08	\$ 0.70
3/1/2022	5,000	Options	\$ 1.05	\$ 0.31
3/31/2022	1,706,282	Options	\$ 1.04	\$ 0.51
3/31/2022	269,297	Restricted Stock Units	\$ -	\$ -
	<u>2,202,579</u>			

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

<b>(in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Cost of revenue	\$ 46	\$ 31
Research and development	(30)	25
Sales and marketing	147	139
General and administrative	576	190
<b>Total</b>	<b>\$ 739</b>	<b>\$ 385</b>

### **4. LOSS PER SHARE**

The Company calculates basic loss per share using the weighted average number of shares of Aspira common stock outstanding during the period. Because the Company is in a net loss position, diluted loss per share is calculated using the weighted average number of shares of Aspira common stock outstanding and excludes the effects of 11,388,605 and 10,514,070 potential shares of Aspira common stock as of March 31, 2022 and 2021, respectively, that are anti-dilutive. Potential shares of Aspira common stock include incremental shares of Aspira common stock issuable upon the exercise of stock options and unvested restricted stock units.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### ***Forward-Looking Statements***

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

These statements involve a number of risks and uncertainties. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements speak only as of the date on which this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission (the "SEC"), and, except as required by law, Aspira Women's Health Inc. ("Aspira" and, together with its subsidiaries, the "Company," "we," "our," or "us") does not assume any obligation to update, amend or clarify them to reflect events, new information or circumstances occurring after such date.

Examples of forward-looking statements include, without limitation:

- projections or expectations regarding our future test volumes, revenue, cost of revenue, operating expenses, research and development expenses, gross profit margin, cash flow, results of operations and financial condition;
- our plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological diseases, including additional pelvic disease conditions such as endometriosis and, benign pelvic mass monitoring in addition to genetics risk assessment, including breast and ovarian cancer hereditary risk assessment and carrier screening;
- our planned business strategy and strategic business drivers and the anticipated effects thereof, including partnerships such as those based on our Aspira Synergy product, as well as other strategies, specimen collaboration and licensing;
- plans to expand our existing products OVA1, OVERA, OVA1plus, Aspira GenetiX and Aspira Synergy on a global level, and to launch and commercialize our new products, OVAWatch (previously OVASight), EndoCheck and OVAInherit;
- plans to develop new algorithms, molecular diagnostic tests, products and tools and otherwise expand our product offerings, including plans to develop a product using genetics, proteins and other modalities to assess the risk of developing cancer when carrying a pathogenic variant associated with hereditary breast and ovarian cancer that is difficult to detect through a diagnostic test;
- plans to establish payer coverage and secure contracts for Aspira GenetiX, OVAWatch, EndoCheck and OVAInherit separately and expand current coverage and secure contracts for OVA1;
- plans that would address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and other issues in the fields of oncology and women's health;
- anticipated efficacy of our products, product development activities and product innovations, including our ability to improve sensitivity and specificity over traditional diagnostic biomarkers;
- expected competition in the markets in which we compete;
- plans with respect to Aspira Labs, Inc. ("ASPIRA LABS"), including plans to expand or consolidate ASPIRA LABS' testing capabilities;
- expectations regarding continuing future services provided by Quest Diagnostics Incorporated;
- plans to develop informatics products and develop and perform laboratory developed tests ("LDTs");
- FDA oversight changes of LDTs;
- plans to develop a race or ethnicity-specific pelvic mass risk assessment;
- expectations regarding existing and future collaborations and partnerships for our products, including plans to enter into decentralized arrangements for our Aspira Synergy product;
- plans regarding future publications;

expectations regarding potential collaborations with governments, legislative bodies and advocacy groups to enhance awareness and drive policies to provide broader access to our tests;  
 our ability to continue to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests within the United States and internationally, as applicable;  
 our continued ability to expand and protect our intellectual property portfolio;  
 anticipated liquidity, capital requirements and future losses;  
 expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations;  
 expectations regarding the results of our clinical research studies and our ability to recruit patients to participate in such studies;  
 our ability to use our net operating loss carryforwards and anticipated future tax liability under U.S. federal and state income tax legislation;  
 expected market adoption of our diagnostic tests, including OVA1, OVERA, OVA1plus, as well as our offerings of Aspira GenetiX and Aspira Synergy platform;  
 expectations regarding our ability to launch new products we develop or license, co-market or acquire new products;  
 expectations regarding the size of the markets for our products;  
 expectations regarding reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans;  
 plans to use each of AbbVie Inc. serum samples and ObsEva S.A. plasma samples in EndoCheck product validation studies;  
 plans with respect to EndoCheck whether or not the FDA designates it a Breakthrough Device;  
 expected target launch timing for OVAWatch and EndoCheck;  
 expectations regarding compliance with federal and state laws and regulations relating to billing arrangements conducted in coordination with laboratories;  
 plans to advocate for legislation and professional society guidelines to broaden access to our products and services; and  
 expectations regarding the impacts resulting from or attributable to the COVID-19 pandemic and actions taken to contain it.

Forward-looking statements are subject to significant risks and uncertainties, including those discussed in Part I Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2021, that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including impacts resulting from or relating to the COVID-19 pandemic and actions taken to contain it; anticipated use of capital and its effects; our ability to increase the volume of our product sales; failures by third-party payers to reimburse for our products and services or changes to reimbursement rates; our ability to continue developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform LDTs; our ability to comply with Food and Drug Administration ("FDA") regulations that relate to our products and to obtain any FDA clearance or approval required to develop and commercialize medical devices; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; or our suppliers' ability to comply with FDA requirements for production, marketing and post-market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; in the event that we succeed in commercializing our products outside the United States, the political, economic and other conditions affecting other countries; changes in healthcare policy; our ability to comply with environmental laws; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPIRA LABS; our ability to use our net operating loss carryforwards; our ability to use intellectual property; our ability to successfully defend our proprietary technology against third parties; our ability to obtain licenses in the event a third party successfully asserts proprietary rights; the liquidity and trading volume of our common stock; the concentration of ownership of our common stock; our ability to retain key employees; our ability to secure additional capital on acceptable

terms to execute our business plan; business interruptions; the effectiveness and availability of our information systems; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; future litigation against us, including infringement of intellectual property and product liability exposure; and additional costs that may be required to make further improvements to our laboratory operations.

## **Company Overview**

### **Corporate Vision**

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

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

All of our products are focused on gynecologic diseases that cannot be assessed through a traditional biopsy, or can only be detected by invasive procedures in the case of Endometriosis, making our non-invasive blood biopsy more efficient and patient friendly. In 2018 and early 2019, we established medical and advisory support and a Key Opinion Leader Network aligned with our territories in the U.S. In addition to adding to our direct salesforce, in 2021, we added OVA1 and OVA1plus on our technology transfer platform, Aspira Synergy. In 2022, we plan to continue our efforts to commercialize OVA1plus by utilizing select partnerships for distribution, expanding our managed care coverage and contracts in select markets, growing our sales force, increasing adoption with our existing and new customers, and further deploying our Aspira Synergy technology transfer platform. We also plan to develop an LDT series of diagnostic algorithms. In 2021, we expanded access to our tests among Medicaid patients as part of our corporate mission to make the best care available to all women.

Our first LDT algorithm, branded as OVAWatch, focuses on monitoring women with pelvic masses. The OVAWatch manuscript, "Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer," has been accepted for online publication in JCO Clinical Cancer Informatics. This study was a critical step towards the launch of OVAWatch and, as a result, we have shifted to finalizing the commercialization plan which will occur in two phases. Phase I is a single use point-in-time product and Phase II will allow for serial monitoring. We plan to focus on advancing to the commercial phase of the OVAWatch single use product, including driving provider adoption, during the second half of 2022. The timing will depend on the results of a clinical validation study that we expect to complete during the summer of 2022. We believe the single-use product has the potential to significantly expand the addressable market over OVA1plus. The launch of the serial monitoring test remains targeted for 2023 upon publication of data from the ongoing prospective serial monitoring clinical study.

We expect that our second LDT diagnostic algorithm, EndoCheck, will aid in the diagnosis of endometriosis. We also plan to expand our portfolio of products to include OVAnherit, which aims to identify risk of malignancy in those patients who are genetically predisposed to ovarian cancer. This algorithm will include genetics, proteins and other modalities to assess such risk.

To continue our commercialization objectives and reach our financial and operational goals, we require skilled 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.



## Our Business and Products

We currently market and sell the following products and related services: (1) OVA1, a blood test intended as an aid to further assess the likelihood of malignancy in women with an ovarian adnexal mass for which surgery is planned when the physician's independent clinical and radiological evaluation does not indicate malignancy; (2) OVERA, a second-generation biomarker reflex intended to maintain OVA1's high sensitivity while improving specificity; (3) OVA1plus, a reflex offering which uses OVA1 as the primary test and OVERA as a confirmation for OVA1 intermediate range results and leverages the strengths of OVA1's MIA sensitivity and OVERA's (MIA2G) specificity and as a result reduces false elevations by over 40%; (4) Aspira GenetiX, a genetic test for hereditary gynecologic cancer risk, with a core focus on hereditary female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers; and (5) Aspira Synergy, our decentralized testing platform and cloud service for decentralized global access of both protein biomarker and hereditary genetic testing. We plan to make OVA1, OVERA, OVA1plus and Aspira GenetiX and future technology available through Aspira Synergy. Our OVA1 test received FDA *de novo* classification in September 2009. OVA1 comprises instruments, assays, reagents, and the OVACALC software, which includes a proprietary algorithm that produces a risk score. Our OVERA test, which includes an updated version of OVACALC, received FDA 510(k) clearance in March 2016. OVA1 and OVERA each use the Roche cobas 4000, 6000 and 8000 platforms for analysis of proteins. Through March 31, 2022, our product and related services revenue has been limited to revenue largely generated by sales of OVA1, OVA1plus and Aspira GenetiX.

In 2021, we entered into decentralized arrangements with large healthcare networks and physician practices for our Aspira Synergy platform offering specialty and genetic testing solutions. The modules available under Aspira Synergy include our flagship OVA1plus risk assessment, Genetics Carrier Screening, and Genetics Hereditary Cancer solutions. The Company has entered into four technology transfer agreements since the launch of Aspira Synergy. The first two agreements are with two of the nation's largest and leading independent women's healthcare groups which together include approximately 750 providers and serve approximately 950,000 patients annually. The other two agreements are with independent laboratories providing services across five states. In the fourth quarter of 2021, we started receiving specimens related to our OVA1 Aspira Synergy product.

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

OVAWatch has been developed and is validated for use in Aspira's CLIA-certified high complexity lab as a non-invasive risk assessment test for use in conjunction with clinical assessment and imaging to determine ovarian cancer risk for patients with an adnexal mass. The commercialization plan for OVAWatch will occur in two phases. Phase I is a single use, point-in-time risk assessment test and Phase II will allow for serial monitoring. We will focus on advancing to the commercial phase of the OVAWatch single use risk assessment test, including driving provider adoption, during the second half of 2022. The timing will depend on the results of a clinical validation study that we expect to complete this summer. We believe the single-use product has the potential to significantly expand the addressable market over OVA1plus. The launch of the serial monitoring test remains targeted for 2023 upon publication of data from the ongoing prospective serial monitoring clinical study. EndoCheck, an in-development non-invasive blood test to be used in conjunction with other non-surgical modalities, is designed to be an aid in the detection of endometriosis and address the patient population of women who are experiencing moderate to severe pelvic pain to provide non-invasive confirmation that their symptoms are indicative of endometriosis. The goal of this test is to support an early diagnosis and direct appropriate medical management that potentially reduces the progression of disease. Current detection methods for endometriosis require surgery and a surgical biopsy diagnosis and/or visualization diagnosis. EndoCheck is intended to address this large patient population by using a non-invasive solution with both the sensitivity and specificity comparable to surgical biopsy and/or visualization. EndoCheck is being developed as an LDT.

OVAInherit will be designed as a non-invasive high-risk diagnostic tool, intended for those patients with or without a pelvic mass who are genetically predisposed to gynecologic cancer. It will use genetics, proteins and other modalities to assess the likelihood that a woman has an early-stage gynecological cancer that is not visible using traditional ultrasound methodologies, and thereby to aid in early diagnoses. Our OVAInherit related clinical studies, OVA1Nex and OVA360, initiated in late 2019 and early 2020, respectively, are focused on developing data to support a diagnostic test for the early detection of ovarian cancer. Our collaboration work with Harvard Dana-Farber Cancer Institute and Medical University of Lodz Phase 1 Proof of Concept evaluation surpassed all required metrics and based on the outcome data, we have begun implementing Phase 2 of the study. In Phase 2, the team is evaluating the combined potential impact of our protein biomarker algorithms and the investigators' miRNA technology in the development of this assay and platform. We ultimately plan to commercialize each of OVA1, OVERA, OVA1plus, Aspira GenetiX, OVAWatch, EndoCheck, OVAInherit and Aspira Synergy on a global level. We currently hold CE marks for OVA1 and OVERA. In addition, each of OVA1 and OVERA, and the reflex offering, OVA1plus, will be offered on our global testing platform, which will allow both tests to be deployed worldwide.

Outside of the United States, we have studies in process to validate OVERA and OVA1 in specific populations. This includes active international distribution agreements for OVERA with Pro-Genetics LTD in Israel and MacroHealth, Inc. in the Philippines. The MacroHealth, Inc. agreement was our first agreement regarding our decentralized technology, Aspira Synergy, for OVERA specimen testing.

We own and operate ASPIRA LABS, based in Austin, Texas, a Clinical Chemistry and Endocrinology Laboratory accredited by the College of American Pathologists, which specializes in applying biomarker-based technologies to address critical needs in the management of gynecologic cancers and disease. ASPIRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based risk assessment to aid in clinical decision making and advance personalized treatment plans. The lab currently processes our OVA1 and OVERA tests, and we plan to expand the testing to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPIRA LABS. ASPIRA LABS holds a 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.

In the United States, revenue for diagnostic tests comes from several sources, including third-party payers such as insurance companies, government healthcare programs, such as Medicare and Medicaid, client bill accounts and patients. Novitas Solutions, a Medicare contractor, covers and reimburses for OVA1 tests performed in certain states, including Texas. Due to OVA1 tests being performed exclusively at ASPIRA LABS in Texas, the local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. ASPIRA LABS also bills third-party commercial and other government payers as well as client bill accounts and patients for OVA1.

In November 2016, the American College of Obstetricians and Gynecologists ("ACOG") issued Practice Bulletin Number 174 which included OVA1, defined as the "Multivariate Index Assay", outlining ACOG's clinical management guidelines for adnexal mass management. Practice Bulletin Number 174 recommends that obstetricians and gynecologists evaluating women with adnexal masses who do not meet Level A criteria of a low risk transvaginal ultrasound should proceed with Level B clinical guidelines. Level B guidelines state that the physician may use risk assessment tools such as existing CA125 technology or OVA1 ("Multivariate Index Assay") as listed in the bulletin. Based on this, OVA1 achieved parity with CA125 as a Level B clinical recommendation for the management of adnexal masses.

Practice Bulletins summarize current information on techniques and clinical management issues for the practice of obstetrics and gynecology. Practice Bulletins are evidence-based documents, and recommendations are based on the evidence. 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.

In October 2018, ASPIRA LABS launched OVA1plus, a clinical pathway which combines the strengths of OVA1 and OVERA. This offering helps drive earlier ovarian cancer risk detection, which in turn lowers overall healthcare costs and reduces inefficiencies in the care pathway.

## **Recent Developments**

### **Leadership Updates**

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

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

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

### **Business, Coverage and Collaboration Updates**

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

On January 31, 2022, we announced that we entered into agreements to provide testing services to Medicaid plan members in the state of New Hampshire and Washington, D.C. equaling nearly a half million covered lives. The state of New Hampshire covers 200,000 lives and Washington D.C. covers 265,000 lives under their respective Medicaid programs. With the addition of these plans, Aspira is now credentialed to provide its OVA1 testing to nearly 80% of the Medicaid population in the U.S., totaling approximately 60 million lives. In addition, during the first quarter the Company has been credentialed with Medicaid for the States of Maryland and Maine, adding an additional 500,000 covered Medicaid lives.

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

During the first quarter of 2022, we executed a commercial reorganization resulting in the separation of a number of employees. The changes were aimed at enhancing our national sales force and driving the accelerated adoption of OVA1plus as the standard of care for early risk detection of ovarian cancer in women who have been planned for surgery. The organizational changes resulted in the recording of one-time severance, separation, and settlement payments in the first quarter of approximately \$1,284,000 including estimated future payouts, partially offset by insurance reimbursement of \$523,000. See Note 2 to the condensed consolidated financial statements.

### **COVID-19 Pandemic**

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. The novel coronavirus has since spread to over 100 countries, including every state in the United States. In March 2020, the World Health Organization declared COVID-19, the disease caused by the novel coronavirus, a pandemic, and the United States declared a national emergency with respect to the coronavirus outbreak. This

outbreak has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. In order to reduce the impact of limitations on visiting physician offices due to closures and quarantines, we implemented other mechanisms for reaching physicians such as virtual sales representative meetings, Key Opinion Leader presentations, and increased digital sales and marketing. Patient enrollment for our planned clinical research studies has been slower than originally planned due to the impact of clinic closures and patients not seeking medical care in some states, which has led to delays in the completion of such studies.

In the first quarter of 2022, a resurgence of COVID-19 cases depressed our average daily test volume in January. Although our daily test volume recovered later in the quarter, we believe given the potential for future resurgences of COVID-19 cases and the variety of federal and state actions taken to contain them, we are unable to estimate the potential future impact of the COVID-19 pandemic on our business, results of operations or cash flows as of the date of the filing of this Form 10-Q.

In addition, as of the date of the filing of this Form 10-Q, we have approximately two months of reagents, one of our key testing supplies, in stock, depending on volume of tests performed, and we are working with the manufacturer to ensure a consistent supply over the next six months. As previously disclosed, we have put in place staffing and reagent contingency plans to ensure there is no down time at our lab. We believe the lab could continue to operate in the event any isolated infection were to impact a portion of the workforce. The full impact of the COVID-19 pandemic continues to evolve as of the date of the filing of this Form 10-Q.

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

- 1) Maximizing the existing OVA1plus opportunity by actively pursuing broad physician adoption and payer coverage;
- 2) Leveraging our existing database and specimen bank while building our specimen and data repository of gynecologic pelvic mass patients;
- 3) Expanding our product offerings to aid in diagnostic and risk stratification for additional women's health diseases with a focus on pelvic disease conditions such as pelvic mass monitoring and endometriosis by adding additional gynecologic bio-analytic solutions involving biomarkers, genetics, other modalities (e.g., imaging), clinical risk factors and patient data; this may occur via licensing or other business development and merger and acquisition opportunities that represent synergistic offerings in women's health;
- 4) Coupling our OVA products with an individual's hereditary genetic risk to refine ovarian cancer risk assessment for high-risk populations; and
- 5) Establishing a proprietary decentralization platform, Aspira Synergy, to allow large healthcare networks and physician practices to access OVA and Aspira GenetiX algorithms as a technology transfer service, while also obtaining access to de-identified data through these arrangements to allow us to enhance our algorithm development on a cost-effective basis.

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

### **Recent Publications**

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

The OVAWatch manuscript, "Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer," has been accepted for publication in the Journal of Clinical Oncology Clinical Cancer Informatics. The Publication is forthcoming and will be on-line. The Company has prepared an application for a Proprietary Laboratory Analyses code with the American Medical Association for the OVAWatch test to distinguish it from OVA1plus with an expectation that Novitas and other payers will apply the OVA1plus Centers

for Medicare & Medicaid Services fee to OVAWatch, ensuring consistent coverage and pricing for both OVA products.

### **Critical Accounting Policies and Estimates**

Our product revenue is generated by performing diagnostic services using our OVA1, OVERA, OVA1plus or Aspira GenetiX tests, and the service is completed upon the delivery of the test result to the prescribing physician. The entire transaction price is allocated to the single performance obligation contained in a contract with a patient. Under ASC Topic 606, *Revenue from Contracts with Customers*, all revenue is recognized upon completion of the OVA1, OVERA, OVA1plus or Aspira GenetiX test and delivery of test 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, we consider factors such as payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and us, and any developments or changes that could impact reimbursement. These estimates require significant judgment by management. For OVA1, OVERA, OVA1plus and Aspira GenetiX tests, 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.

### **Results of Operations - Three Months Ended March 31, 2022 Compared to Three Months Ended March 31, 2021**

The selected summary financial and operating data of the Company for the three months ended March 31, 2022 and 2021 were as follows:

<b>(dollars in thousands)</b>	<b>Three Months Ended</b>		<b>Increase (Decrease)</b>	
	<b>March 31,</b>		<b>Amount</b>	<b>%</b>
	<b>2022</b>	<b>2021</b>		
Revenue:				
Product	\$ 1,835	\$ 1,416	\$ 419	30
Genetics	58	80	(22)	(28)
Total revenue	1,893	1,496	397	27
Cost of revenue:				
Product	857	655	202	31
Genetics	75	238	(163)	(68)
Total cost of revenue	932	893	39	4
Gross profit	961	603	358	59
Operating expenses:				
Research and development	1,348	872	476	55
Sales and marketing	4,497	3,108	1,389	45
General and administrative	4,363	2,509	1,854	74
Total operating expenses	10,208	6,489	3,719	57
Loss from operations	(9,247)	(5,886)	(3,361)	57
Interest expense, net	(18)	(24)	6	25
Other expense, net	(3)	(10)	7	70
Net loss	\$ (9,268)	\$ (5,920)	\$ (3,348)	57

**Product Revenue.** Product revenue was \$1,835,000 for the three months ended March 31, 2022, compared to \$1,416,000 for the same period in 2021. Revenue for ASPIRA LABS is recognized when the OVA1, OVERA, or OVA1plus test is completed based on estimates of what we expect to ultimately realize. The 30% product revenue increase is due to an increase in OVA1 test volume compared to the prior year, in addition to a

higher revenue average unit price ("AUP"), which increased from \$375 in the first quarter of 2021 to \$380 in the first quarter of 2022. This increase was primarily driven by an increased volume of tests performed for higher AUP payers, such as those for Medicare and insurance carriers, along with a decreased volume of tests performed for lower AUP payers, such as Medicaid and patient payers.

Medicaid represents approximately 11.6% of volume in the three months ended March 31, 2022, at an AUP of \$89. Our OVA1plus AUP without Medicaid was \$418 for the three months ended March 31, 2022, compared to \$411 for the same period in 2021. Product revenue increased 1% sequentially during the first quarter 2022 as compared to the fourth quarter 2021.

The number of OVA1plus tests performed increased 28% to 4,819 during the three months ended March 31, 2022, compared to 3,775 OVA1plus tests for the same period in 2021. This increase was due to increased access to provider offices, patients' return to physician visits, and increased investment in our current commercial channel. The number of OVA1plus tests performed only increased 1% sequentially during the first quarter 2022 as compared to the fourth quarter 2021 as a result of access restrictions due to the COVID-19 resurgence in January 2022. We expect revenue to increase in 2022 due to investing in key salesforce hires and strategic product development.

**Genetics Revenue.** Genetics revenue was \$58,000 for the three months ended March 31, 2022, compared to \$80,000 for the same period in 2021. Although there was a decrease as compared to the same period last year, Genetics revenue increased 61% as compared to the fourth quarter of 2021. Revenue for Aspira GenetiX is recognized when the Aspira GenetiX test is completed based on estimates of what we expect to ultimately realize. The 28% genetics revenue decrease is primarily due to decreased volumes as compared to the same period in 2021. The revenue per test performed remained flat at \$456 from the same period in 2021.

**Cost of Revenue – Product.** Cost of product revenue was \$857,000 for the three months ended March 31, 2022, compared to \$655,000 for the same period in 2021, representing an increase of \$202,000, or 31%, due primarily to increased personnel costs, lab supplies, and shipping costs due to the increase in tests performed compared to the prior year.

**Cost of Revenue – Genetics.** Cost of genetics revenue, which consisted primarily of personnel costs and consulting expense after the launch of Aspira GenetiX, was \$75,000 for the three months ended March 31, 2022, compared to \$238,000 for the same period in 2021. The decrease in cost was due to a decrease of \$108,000 in personnel costs, due to a decrease in volume of tests performed as compared to the same period in 2021.

**Gross Profit Margin.** Gross profit margin for OVA1plus remained relatively flat at 53.3% for the three months ended March 31, 2022, compared to 54.2% for the same period in 2021.

**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 three months ended March 31, 2022 increased by \$476,000, or 55%, compared to the same period in 2021. This increase was primarily due to clinical validity and product development costs related to OVAWatch, our third-generation product, as well as investments in Aspira Synergy, increased personnel expenses, consulting expenses associated with EndoCheck regulatory clearance and severance paid in relation to our reorganization of \$132,000. We expect research and development expenses to increase in 2022, relative to 2021, as a result of increased projects and clinical studies.

**Sales and Marketing Expenses.** Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses. These expenses include the costs of educating physicians and other healthcare professionals regarding OVA1, OVERA, OVA1plus and Aspira GenetiX. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the three months ended March 31, 2022 increased by \$1,389,000, or 45%, compared to the same period in 2021. This increase was primarily due to increased personnel, severance paid in relation to our reorganization,

commissions, and travel and entertainment costs. We expect sales and marketing expenses to increase in 2022, relative to 2021, due to investing in key strategic hires and product portfolio expansion.

During the first quarter of 2022, we executed a commercial reorganization resulting in the separation of a number of employees. The changes were aimed at enhancing our national sales force and driving the accelerated adoption of OVA1plus as the standard of care for early risk detection of ovarian cancer in women who have been planned for surgery. The organizational changes resulted in the recording of one-time severance, separation, and settlement payments in the first quarter of approximately \$1,284,000 including estimated future payouts, of which \$1,085,000 paid related to sales and marketing, partially offset by insurance reimbursement of \$523,000, of which \$503,000 related to sales and marketing.

**General and Administrative Expenses.** General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses and other infrastructure expenses. General and administrative expenses for the three months ended March 31, 2022 increased by \$1,854,000, or 74%, compared to the same period in 2021. This increase was primarily due to increased personnel expenses of \$984,000, consulting expenses of \$164,000, and stock compensation expenses of \$353,000. Severance paid to general and administrative-related personnel was immaterial. We expect general and administrative expenses to increase in 2022, relative to 2021.

### ***Liquidity and Capital Resources***

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

The Company has incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately \$480,996,000 as of March 31, 2022. The Company also expects to incur a net loss and negative cash flows from operations for 2022.

As discussed in Note 2 to the condensed consolidated financial statements, in March 2016, the Company entered into a loan agreement (as amended on March 7, 2018 and April 3, 2020, the "DECD Loan Agreement") with the State of Connecticut Department of Economic and Community Development (the "DECD"), pursuant to which it may borrow up to \$4,000,000 from the DECD.

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

Under the terms of the DECD Loan Agreement, we may be eligible for forgiveness of up to \$1,500,000 of the principal amount of the loan if we achieve certain job creation and retention milestones by December 31, 2022. Conversely, if we are either unable to retain 25 full-time employees with a specified average annual salary for a consecutive two-year period or do not maintain our Connecticut operations through March 22, 2026, the DECD may require early repayment of a portion or all of the loan plus a penalty of 5% of the total funded loan. For additional information, see Note 2 of our consolidated financial statements.

As discussed in Note 2 to the condensed consolidated financial statements, on May 1, 2020, we obtained the Paycheck Protection Program loan (the "PPP Loan") from BBVA USA in the aggregate amount of approximately \$1,006,000. We applied for forgiveness of the PPP Loan in March 2021, and, effective May 27, 2021, the SBA confirmed the waiver of our repayment of the PPP Loan, which was recognized as a gain in other income in 2021. We remain subject to an audit of the PPP loan. There is no assurance that we will not be required to repay all or a portion of the PPP Loan as a result of any such audit.

As discussed in Note 3 to the condensed consolidated financial statements, on February 8, 2021, the Company completed a public offering (the "2021 Offering") resulting in net proceeds of approximately \$47,858,000, after deducting underwriting discounts and offering expenses. There was a change in estimate in the third quarter of 2021 in the amount of \$138,000 relating to an expense reversal of offering costs.

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

- Making any acquisition with a value greater than \$2 million;
- Offering, selling or issuing any securities senior to Aspira's common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to Aspira's common stock;
- Taking any action that would result in a change in control of the Company or an insolvency event; and
- Paying or declaring dividends on any securities of the Company or distributing any assets of the Company other than in the ordinary course of business or repurchasing any outstanding securities of the Company.

The foregoing rights terminate for a primary investor when that investor ceases to beneficially own less than 50% of the shares and warrants (taking into account shares issued upon exercise of the warrants), in the aggregate, that were purchased at the closing of the 2013 private placement.

As mentioned, we have incurred significant net losses and negative cash flows from operations since inception, and we expect to continue to incur a net loss and negative cash flows from operations in 2022. At March 31, 2022 we had an accumulated deficit of (\$480,996,000) and stockholders' equity of \$21,744,000. As of March 31, 2022, we had \$26,855,000 of cash and cash equivalents (excluding restricted cash of \$250,000), \$5,778,000 of current liabilities, and working capital of \$23,661,000. There can be no assurance that we will achieve or sustain profitability or positive cash flow from operations. While we expect to grow revenue through ASPIRA LABS, there is no assurance of our ability to generate substantial revenues and cash flows from ASPIRA LABS' operations. We expect revenue from our products to be our only material, recurring source of cash in 2022. In addition, the impact of the COVID-19 pandemic and actions taken to contain it on our liquidity for 2022 cannot be estimated as of the date of the filing of this Form 10-Q. However, we believe that our cash and cash equivalents will be sufficient to fund our operations for the next 12 months from the date of the filing of this Form 10-Q.

While we believe that we have sufficient capital to fund our operations for the next 12 months, we are currently evaluating our capital needs beyond the next 12 months, which may involve additional capital raises and/or other financing activities in order to continue to fund operations at current cash expenditure levels. We may take further action to protect our liquidity position, including in the event that our existing cash on hand is not sufficient to fund our operations, meet our capital requirements or satisfy our anticipated obligations as they become due. 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.



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

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

Net cash used in operating activities was \$10,173,000 for the three months ended March 31, 2022, resulting primarily from the net loss reported of \$9,268,000, which includes non-cash expenses in the amount of \$838,000 related to stock compensation expense and \$64,000 related to depreciation and amortization, and changes in accounts payable, accrued and other liabilities of \$1,705,000.

Net cash used in operating activities was \$5,255,000 for the three months ended March 31, 2021, resulting primarily from the net loss reported of \$5,920,000, which includes non-cash expenses in the amount of \$489,000 related to stock compensation expense and \$90,000 related to depreciation and amortization, and offset by changes in accounts payable, accrued and other liabilities of \$291,000.

Net cash used in investing activities was \$82,000 and \$41,000 for the three months ended March 31, 2022 and 2021, respectively, which consisted of property and equipment purchases.

Net cash used in financing activities was \$70,000 for the three months ended March 31, 2022, which primarily included principal payments on the DECD loan. Net cash provided by financing activities was \$48,034,000 for the three months ended March 31, 2021, which resulted primarily from the February 2021 public offering, resulting in net proceeds to the Company of approximately \$47,720,000, after deducting underwriting discounts and offering expenses of \$516,000. There was a change in estimate in the third quarter of 2021 in the amount of \$138,000 relating to an expense reversal of offering costs.

We have significant NOL carryforwards as of March 31, 2022 for which a full valuation allowance has been provided due to our history of operating losses. Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state provisions may restrict our ability to use our NOL credit carryforwards due to ownership change limitations occurring in the past or that could occur in the future. These ownership changes may also limit the amount of NOL credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

Legislation commonly referred to as the Tax Cuts and Jobs Act was enacted in December 2017. As a result of the Tax Cuts and Jobs Act of 2017, federal NOLs arising before January 1, 2018, and federal NOLs arising after January 1, 2018, are subject to different rules. The Company's pre-2018 federal NOLs will expire in varying amounts from 2022 through 2037, if not utilized, and can offset 100% of future taxable income for regular tax purposes. Any federal NOLs arising after January 1, 2018, can generally be carried forward indefinitely and can offset up to 80% of future taxable income. State NOLs will expire in varying amounts from 2022 through 2037 if not utilized. Our ability to use our NOLs during this period will be dependent on our ability to generate taxable income, and the NOLs could expire before the Company generates sufficient taxable income. The Company's ability to use NOL carryforwards may be restricted due to ownership change limitations occurring in the past or that could occur in the future, as required by Section 382, as well as similar state specific provisions. These ownership changes may also limit the amount of NOL carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

Our management believes that Section 382 ownership changes occurred as a result of our follow-on public offerings in 2011, 2013 and 2015. Any limitation may result in the expiration of a portion of the NOL carryforwards before utilization and any NOL carryforwards that expire prior to utilization as a result of such

limitations will be removed from deferred tax assets with a corresponding reduction of our valuation allowance. Due to the existence of a valuation allowance, it is not expected that such limitations, if any, will have an impact on our results of operations or financial position.

### **Off-Balance Sheet Arrangements**

As of March 31, 2022, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our condensed consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Per Item 305(e) of Regulation S-K, the information called for by this Item 3 is not required.

### **ITEM 4. 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 March 31, 2022. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2022, our disclosure controls and procedures were effective.

#### ***Changes in internal controls over financial reporting.***

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially and adversely affect our results of operations, cash flows and financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of March 31, 2022, that, in the opinion of management, will have a material adverse effect on our financial position, results of operations or cash flows.

## **ITEM 1A. RISK FACTORS**

There have been no material changes to our risk factors from those disclosed under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K, filed with the SEC on March 31, 2022 (the “2021 Annual Report”). The risks and uncertainties described in our 2021 Annual Report 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 or results of operations.

**ITEM 6. EXHIBITS** The following exhibits are filed or incorporated by reference with this report as indicated below:

Exhibit Number	Exhibit Description	Incorporated by Reference		Exhibit	Filing Date	Filed Herewith
		Form	File No.			
<a href="#"><u>3.1</u></a>	<a href="#"><u>Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated January 22, 2010</u></a>	8-K	000-31617	3.1	January 25, 2010	
<a href="#"><u>3.2</u></a>	<a href="#"><u>Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation, effective June 19, 2014</u></a>	10-Q	001-34810	3.2	August 14, 2014	
<a href="#"><u>3.3</u></a>	<a href="#"><u>Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated June 11, 2020</u></a>	8-K	001-34810	3.1	June 11, 2020	
<a href="#"><u>3.4</u></a>	<a href="#"><u>Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock</u></a>	8-K	001-34810	4.1	April 17, 2018	
<a href="#"><u>3.5</u></a>	<a href="#"><u>Amended and Restated Bylaws of Aspira Women's Health Inc., effective February 23, 2022</u></a>	8-K	001-34810	3.1	February 28, 2022	
<a href="#"><u>10.1</u></a>	<a href="#"><u>Amended and Restated Employment Agreement between Aspira Women's Health Inc. and Valerie B. Palmieri effective March 1, 2022*#</u></a>	8-K	<u>001-34810</u>	<u>10.1</u>	<u>February 28, 2022</u>	
<a href="#"><u>10.2</u></a>	<a href="#"><u>Employment Agreement between Aspira Women's Health Inc. and Nicole Sandford effective March 1, 2022*#</u></a>	8-K	<u>001-34810</u>	<u>10.2</u>	<u>February 28, 2022</u>	
<a href="#"><u>31.1</u></a>	<a href="#"><u>Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>					✓
<a href="#"><u>31.2</u></a>	<a href="#"><u>Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>					✓
<a href="#"><u>32.1</u></a>	<a href="#"><u>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</u></a>					✓✓
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL")					✓
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					✓
✓	Filed herewith					
✓✓	Furnished herewith					
#	Management contract or compensatory plan or arrangement.					
*	Portions of this exhibit have been omitted in accordance with SEC rules					

## SIGNATURES

Pursuant to the requirements 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: May 11, 2022

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

Date: May 11, 2022

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