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

FORM 10-Q

(Mark One)
þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-34810

Aspira Women's Health Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0595156**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
12117 Bee Caves Road, Building Three, Suite 100, Austin, Texas	**78738**
(Address of principal executive offices)	(Zip Code)

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

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

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

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 þ 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 þ No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer þ	Smaller reporting company þ
	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 þ
As of November 4, 2022, the registrant had 124,445,639 shares of common stock, par value $0.001 per share, outstanding.

ASPIRA WOMEN'S HEALTH INC.

FORM 10-Q
For the Quarter Ended September 30, 2022
Table of Contents

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℠ , OVA1PLUS®, OVAWATCH℠ ENDOCHECK™, OVAINHERIT™, ASPIRA SYNERGY℠, and OVA360℠, ASPIRA IVD® , OVASUITE℠, AND YOUR HEALTH, OUR PASSION®.

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)

	September 30, 2022	December 31, 2021
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 20,551	$ 37,180
Accounts receivable, net of allowance of $6 and $23, respectively	1,201	1,027
Prepaid expenses and other current assets	944	1,624
Inventories	280	174
Total current assets	22,976	40,005
Property and equipment, net	417	464
Right-of-use assets	299	346
Restricted cash	250	250
Other assets	-	14
Total assets	$ 23,942	$ 41,079
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,893	$ 1,501
Accrued liabilities	4,988	5,299
Current portion of long-term debt	343	201
Short-term debt	-	779
Lease liability	73	60
Total current liabilities	7,297	7,840
Non-current liabilities:		
Long-term debt	2,426	2,718
Lease liability	293	349
Warrant liabilities	2,748	-
Total liabilities	12,764	10,907
Commitments and contingencies (Note 2)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at September 30, 2022 and December 31, 2021; 124,445,639 and 112,138,741 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	124	112
Additional paid-in capital	504,851	501,788
Accumulated deficit	(493,797)	(471,728)
Total stockholders' equity	11,178	30,172
Total liabilities and stockholders' equity	$ 23,942	$ 41,079

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product	$ 2,037	$ 1,617	$ 5,890	$ 4,753
Genetics	35	49	141	208
Total revenue	2,072	1,666	6,031	4,961
Cost of revenue[1]:				
Product	875	715	2,768	2,209
Genetics	41	202	180	704
Total cost of revenue	916	917	2,948	2,913
Gross profit	1,156	749	3,083	2,048
Operating expenses:				
Research and development[2]	2,157	1,518	4,915	3,861
Sales and marketing[3]	3,950	5,083	12,027	12,209
General and administrative[4]	4,746	3,839	13,305	9,627
Total operating expenses	10,853	10,440	30,247	25,697
Loss from operations	(9,697)	(9,691)	(27,164)	(23,649)
Change in fair value of warrant liabilities	5,004	-	5,004	-
Interest income (expense), net	18	(14)	(10)	(35)
Other income (expense), net	117	(2)	101	983
Net loss	$ (4,558)	$ (9,707)	$ (22,069)	$ (22,701)
Net loss per share - basic and diluted	$ (0.04)	$ (0.09)	$ (0.19)	$ (0.20)
Weighted average common shares used to compute basic and diluted net loss per common share	117,118,136	112,077,133	113,863,079	110,904,824
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$ (23)	$ 49	$ 64	$ 137
(2) Research and development	65	115	114	236
(3) Sales and marketing	76	368	281	843
(4) General and administrative	428	646	1,535	1,733

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	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
Balance at March 31, 2022	112,141,741	$ 112	$ 502,628	$ (480,996)	$ 21,744
Net loss	-	-	-	(8,243)	(8,243)
Common stock issued in conjunction with exercise of stock options	20,000	-	11	-	11
Common stock issued for restricted stock awards	134,647	-	140	-	140
Stock-based compensation expense	-	-	470	-	470
Balance at June 30, 2022	112,296,388	$ 112	$ 503,249	$ (489,239)	$ 14,122
Net loss	-	-	-	(4,558)	(4,558)
Common stock and warrants issued in conjunction with follow-on public offering, net of issuance costs	12,000,000	12	1,056	-	1,068
Common stock issued for restricted stock awards	149,251	-	95	-	95
Stock-based compensation expense	-	-	451	-	451
Balance at September 30, 2022	124,445,639	$ 124	$ 504,851	$ (493,797)	$ 11,178

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	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
Balance at March 31, 2021	111,716,852	$ 112	$ 498,199	$ (445,986)	$ 52,325
Net loss	-	-	-	(7,074)	(7,074)
Common stock issued in conjunction with exercise of stock options	305,090	-	304	-	304
Common stock issued for restricted stock awards	36,092	-	267	-	267
Common stock issued in conjunction with public offering, net of issuance costs	-	-	1	-	1
Stock-based compensation expense	-	-	1,015	-	1,015
Balance at June 30, 2021	112,058,034	$ 112	$ 499,786	$ (453,060)	$ 46,838
Net loss	-	-	-	(9,707)	(9,707)
Common stock issued in conjunction with exercise of stock options	27,500	-	58	-	58
Common stock issued for restricted stock awards	14,515	-	108	-	108
Common stock issued in conjunction with public offering, net of issuance costs	-	-	137	-	137
Stock-based compensation expense	-	-	1,070	-	1,070
Balance at September 30, 2021	112,100,049	$ 112	$ 501,159	$ (462,767)	$ 38,504

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)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (22,069)	$ (22,701)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	4	35
Depreciation and amortization	195	238
Stock-based compensation expense	1,994	2,949
Change in fair value of warrant liabilities	(5,004)	-
Loss on sale and disposal of property and equipment	10	1
Forgiveness of PPP loan	-	(1,006)
Changes in operating assets and liabilities:		
Accounts receivable	(174)	(238)
Prepaid expenses and other assets	694	262
Inventories	(106)	(107)
Accounts payable, accrued liabilities and other liabilities	(653)	821
Net cash used in operating activities	(25,109)	(19,746)
Cash flows from investing activities:		
Purchase of property and equipment	(158)	(154)
Net cash used in investing activities	(158)	(154)
Cash flows from financing activities:		
Principal repayment of DECD loan	(196)	(148)
Proceeds from issuance of common stock from exercise of stock options	13	679
Proceeds from public offering	9,000	48,236
Payment of issuance costs for public offering	(179)	(378)
Net cash provided by financing activities	8,638	48,389
Net (decrease) increase in cash, cash equivalents and restricted cash	(16,629)	28,489
Cash, cash equivalents and restricted cash, beginning of period	37,430	16,631
Cash, cash equivalents and restricted cash, end of period	$ 20,801	$ 45,120
Reconciliation to Condensed Consolidated Balance Sheet:		
Cash and cash equivalents	$ 20,551	$ 44,870
Restricted cash	250	250
Unrestricted and restricted cash and cash equivalents	$ 20,801	$ 45,120
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	57	57
Supplemental disclosure of noncash investing and financing activities:		
Net decrease in right-of-use assets	(47)	(45)
Forgiveness of PPP loan	-	(1,006)
Fair value of warrants issued in conjunction with common stock offering	7,752	-

See accompanying notes to the unaudited condensed consolidated financial statements.

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 (4) Aspira Synergy, the Company's decentralized testing platform and cloud service for decentralized global access of protein biomarker testing. The Company continues to make Ova1, Overa, and Ova1Plus, and plans to make 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. Revenue from these sources (in addition to revenue from Aspira GenetiX) is included in total revenue in the results of operations for the nine months ended September 30, 2022.

Liquidity

As of September 30, 2022, the Company had $20,551,000 of cash and cash equivalents (excluding restricted cash of $250,000), an accumulated deficit of approximately ($493,797,000), and working capital of $15,679,000. For the nine months ended September 30, 2022, the Company incurred a net loss of ($22,069,000) and used cash in operations of ($25,109,000). 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. Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern. The condensed consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

The Company expects to raise capital through sources that may include public or private equity offerings, debt financings, the exercise of common stock warrants, collaborations, licensing arrangements, grants and government funding and strategic alliances. However, additional funding may not be available when needed or on terms acceptable to the Company. If the Company is unable to obtain additional capital, it may not be able to continue sales and marketing, research and development, or other operations on the scope or scale of current activity, and that could have a material adverse effect on the Company's business, results of operations and financial condition.

On June 1, 2022, the Company received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying the Company that, for the preceding 30 consecutive business days, the closing bid price for the Company's common stock was below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule"). As provided in the Nasdaq rules, the Company has 180 calendar days, or until November 28, 2022, to regain compliance with the Minimum Bid Price Rule. The Company may achieve compliance during this period if the closing bid price of Aspira common stock is at least $1.00 per share for a minimum of 10 consecutive business

days. If the Company fails to regain compliance on or prior to November 28, 2022, the Company may be eligible for an additional 180-calendar day compliance period, which would extend the deadline until May 27, 2023. There is no assurance that the Company will be able to regain compliance by the November 28, 2022 deadline or the additional 180-calendar day extended deadline, and there is no assurance that the Company will otherwise maintain compliance with this or any of the other Nasdaq continued listing requirements.

The COVID-19 pandemic has severely impacted global economic activity, and many countries and many states in the United States reacted to it by instituting quarantines, mandating business and school closures and restricting travel periodically throughout the pandemic. Patient enrollment for the Company's planned clinical research studies of serial draws of the Company's OvaNex study 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 associated with potential resurgences 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 September 30, 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 September 30, 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.

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

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. While the Company is evaluating the effect of adopting this new accounting guidance, its effect will largely depend on the composition and credit quality of the Company's portfolio of financial assets and the economic conditions at the time of adoption.

In August 2020, the Financial Accounting Standards Board issued Accounting Standard Update No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). This update was issued to assist in simplifying the accounting for convertible instruments. This ASU 2020-06 is scheduled to be effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is in the process of evaluating the impact of this standard on its condensed 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. The carrying value approximates fair value, as the interest represents market prices for similar types of borrowing arrangements.

Long-term debt consisted of the following:

(in thousands)	**September 30, 2022**	**December 31, 2021**
DECD loan, net of issuance costs	$ 2,769	$ 2,919
Less: Current portion, net of issuance costs	(343)	(201)
Total long-term debt, net of issuance costs	$ 2,426	$ 2,718

As of September 30, 2022, the annual amounts of future minimum principal payments due under the Company's contractual obligation are shown in the table below. Unamortized debt issuance costs for the DECD loan were $12,000.

	Payments Due by Period						
(in thousands)	**Total**	**2022**	**2023**	**2024**	**2025**	**2026**	**Thereafter**
DECD Loan	$ 2,781	$ 52	$ 406	$ 452	$ 461	$ 341	$ 1,069
Total	$ 2,781	$ 52	$ 406	$ 452	$ 461	$ 341	$ 1,069

Accrued Liabilities

The following table describes the principal components of accrued liabilities on the Company's condensed consolidated balance sheet as of:

(in thousands)	September 30, 2022	December 31, 2021
Payroll and benefits related expenses	$ 3,405	$ 2,652
Collaboration and research agreements expenses	349	382
Professional services	764	1,992
Other accrued liabilities	470	273
Total accrued liabilities	$ 4,988	$ 5,299

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 $0 and $779,000 as of September 30, 2022 and December 31, 2021, respectively. This note was 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. 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 and administrative offices are located in Trumbull, Connecticut. The Company's Austin, Texas lease, which expires on January 31, 2023, has no automatic renewal or renewal option. The Company's Texas lease has a term of 12 months. The Company recognizes 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 the 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 and nine months ended September 30, 2022 and 2021 is shown in the table below (in thousands).

		Three Months Ended September 30,	
Lease Cost	**Classification**	**2022**	**2021**
Operating rent expense			
	Cost of revenue	$ 20	$ 14
	Research and development	6	13
	Sales and marketing	9	8
	General and administrative	16	16
Variable rent expense			
	Cost of revenue	$ 10	$ 8
	Research and development	5	12
	Sales and marketing	8	11
	General and administrative	16	16

		Nine Months Ended September 30,	
Lease Cost	**Classification**	**2022**	**2021**
Operating rent expense			
	Cost of revenue	$ 59	$ 42
	Research and development	20	35
	Sales and marketing	28	25
	General and administrative	49	51
Variable rent expense			
	Cost of revenue	$ 30	$ 23
	Research and development	16	25
	Sales and marketing	26	30
	General and administrative	51	46

Based on the Company's leases as of September 30, 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	$ 25
2023	106
2024	116
2025	124
2026	64
Total Operating Lease Payments	435
Less: Interest	(69)
Present Value of Lease Liabilities	$ 366

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

Weighted-average remaining lease term (in years)	3.7
Weighted-average discount rate	9.31%

Non-cancellable 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 September 30, 2022 and 2021 totaled $82,000 and $65,000, respectively, and royalty expense for the nine months ended September 30, 2022 and 2021 totaled $236,000 and $190,000, 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. All charges have been settled as of September 30, 2022.

Business Agreements

On August 8, 2022, the Company entered into a sponsored research agreement with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz for the generation of a multi-omic, non-invasive diagnostic aid to identify endometriosis based on circulating microRNAs and proteins. This collaboration is expected to accelerate the Company's development and commercialization of future endometriosis products, such as EndoCheck. Under the terms of and as further described in the agreement, payments of approximately $1,252,000 have or will become due from the Company to the counterparties upon successful completion of certain deliverables in 2022 and 2023 as follows: 68% was paid in August 2022, 15% will become payable upon completion of certain deliverables estimated to occur in the fourth quarter of 2022, and 17% will become payable upon completion of certain deliverables estimated to occur in the second quarter of 2023. As of September 30, 2022 approximately $852,000 has been recorded as expense for the project.

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

2022 Public Offering

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

The Warrants were issued pursuant to a common stock purchase warrant (the "Form of Warrant"). Each Warrant has an initial exercise price equal to $0.88 per share of Common Stock and are exercisable for five years

from the date of issuance. The exercise price and the number of shares of Common Stock issuable upon exercise of the Warrants are subject to adjustment in the event of certain subdivisions and combinations, including by any stock split or reverse stock split, stock dividend, recapitalization or otherwise. The exercise of the Warrants may be limited in certain circumstances if, after giving effect to such exercise, the holder or any of its affiliates would beneficially own (as determined in accordance with the terms of the Warrants) more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding Common Stock immediately after giving effect to the exercise. There is no established trading market available for the Warrants on any securities exchange or nationally recognized trading system.

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

The fair values of the Warrants as of August 22, 2022, the issuance date, and September 30, 2022 were $7,752,000 and $2,748,000, respectively. The fair value of the Warrants was estimated using Black-Scholes pricing model based on the following assumptions:

	September 30, 2022	August 22, 2022
Dividend yield	- %	- %
Volatility	97.5 %	95.0 %
Risk-free interest rate	4.06 %	3.17 %
Expected lives (years)	4.89	5.00
Weighted average fair value	$ 0.229	$ 0.646

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

The fair value of Warrants was affected by changes in inputs to the Black-Scholes option pricing model including the Company's stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 2 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At September 30, 2022, the fair value of all Warrants was $2,748,000, which are classified as a long-term Warrant liability on the Company's balance sheet.

The 2022 Offering resulted in net proceeds to the Company of approximately $7,704,000, after deducting underwriting discounts and offering expenses of $1,296,000. Offering costs were allocated between liability expense and equity based on the fair value of the Warrants of $7,752,000 and the total gross proceeds of $9,000,000. $1,117,000 of offering costs were allocated to the Warrants and were expensed immediately and recorded as selling, general and administrative expense in the condensed unaudited consolidated statement of operations for the three months ended September 30, 2022, resulting in a net impact to the Company's equity of $179,000.

2021 Public Offering

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

Under the 2021 Underwriting Agreement, the Company granted the 2021 Underwriters an option to purchase up to an additional 900,000 shares of Aspira common stock at the public offering price, less the underwriting discount of $0.4875 per share. On February 5, 2021, the 2021 Underwriters notified the Company that they were exercising this option in connection with the closing of the 2021 Offering. The 2021 Offering, including the additional 900,000 shares of Aspira common stock, closed on February 8, 2021 and resulted in net proceeds to the Company of approximately $47,858,000, after deducting underwriting discounts and offering expenses of $378,000. 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 name of which was subsequently changed to the Aspira Women's Health 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 September 30, 2022, 9,873,424 shares of Aspira common stock were subject to outstanding stock options, and 149,249 shares of Aspira common stock were subject to unvested restricted stock awards and a total of 3,531,486 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 3.28% 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.

Grant Date	Number of Shares	Type of Award	Exercise Price / Share	Fair Value / Share
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	$ -	$ -
	2,202,579			

During the three months ended June 30, 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 two years, one- to five-year treasury interest rates of 1.72% to 3.13% and market close prices ranging from $0.52 to $1.05. The Company recorded $109,000 in forfeitures for the three months ended June 30, 2022.

Grant Date	Number of Shares	Type of Award	Exercise Price	Fair Value / Share
4/1/2022	5,000	Options	$ 1.05	$ 0.33
5/2/2022	5,000	Options	$ 0.70	$ 0.22
5/19/2022	60,000	Options	$ 0.55	$ 0.28
6/1/2022	5,000	Options	$ 0.56	$ 0.22
6/23/2022	15,000	Options	$ 0.52	$ 0.21
6/23/2022	78,000	Options	$ 0.52	$ 0.27
6/23/2022	83,799	Options	$ 0.52	$ 0.36
6/23/2022	169,043	Restricted Stock Units	$ -	$ -
	420,842			

During the three months ended September 30, 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 two years, five-year treasury interest rates of 2.79% to 3.50% and market close prices ranging from $0.25 to $0.48. The Company recorded $119,000 in forfeitures for the three months ended September 30, 2022.

Grant Date	Number of Shares	Type of Award	Exercise Price	Fair Value / Share
7/1/2022	5,000	Options	$ 0.73	$ 0.32
7/5/2022	200,000	Options	$ 0.77	$ 0.40
8/1/2022	5,000	Options	$ 0.80	$ 0.35
8/18/2022	122,000	Options	$ 0.92	$ 0.48
9/1/2022	5,000	Options	$ 0.53	$ 0.25
	337,000			

The allocation of employee stock-based compensation expense, including expense reversals due to forfeitures, by functional area for the three and nine months ended September 30, 2022 and 2021 was as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of revenue	$ (27)	$ 44	$ 52	$ 123
Research and development	31	113	21	231
Sales and marketing	76	350	281	814
General and administrative	428	445	1,445	1,236
Total	$ 508	$ 952	$ 1,799	$ 2,404

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 anti-dilutive effects of 10,022,672 and 10,529,341 potential shares of Aspira common stock as of September 30, 2022 and 2021, respectively, in addition to 12,000,000 shares of Aspira common stock issuable upon the exercise of the Warrants outstanding as of September 30, 2022. Potential shares of Aspira common stock and warrants include incremental shares of Aspira common stock issuable upon the exercise of stock options and warrants and the vesting of 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," "targeted," "projects," "aim" 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, price, 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;
- our planned business strategy and strategic business drivers and the anticipated effects thereof, including partnerships such as those based on our Aspira Synergy product, as well as other strategies, specimen collaboration and licensing;
- plans to expand our existing products Ova1, Overa, Ova1Plus and Aspira Synergy on a global level, and to launch and commercialize our new products, OvaWatch, 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 ovarian cancer that is difficult to detect through a diagnostic test;
- plans to establish payer coverage and secure contracts for current and new products, including OvaWatch, EndoCheck and OvaInherit separately and expand current coverage and secure additional contracts for Ova1, Overa and Ova1Plus;
- expectations regarding coverage under Novitas, the Company's Medicare Administrative Carrier for Ova1;
- plans that would address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and other issues in the fields of oncology and women's health;
- anticipated efficacy of our products, product development activities and product innovations, including our ability to improve sensitivity and specificity over traditional diagnostic biomarkers;
- expected competition in the markets in which we compete;
- plans with respect to Aspira Labs, Inc. ("ASPiRA LABS"), including plans to expand or consolidate ASPiRA LABS' testing capabilities;
- expectations regarding continuing future services provided by Quest Diagnostics Incorporated;
- expectations regarding continuing future services provided by BioReference Health, LLC;
- plans to develop informatics products and develop and perform laboratory developed tests ("LDTs");
- Food and Drug Administration ("FDA") oversight changes of LDTs;

plans to develop a race or ethnicity-specific pelvic mass risk assessment;
expectations regarding existing and future collaborations and partnerships for our products, including plans to enter into decentralized arrangements for our Aspira Synergy product and provide and expand access to our risk assessment tests;
plans regarding future publications;
expectations regarding potential collaborations with governments, legislative bodies and advocacy groups to enhance awareness and drive policies to provide broader access to our tests;
our ability to continue to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests within the United States and internationally, as applicable;
our continued ability to expand and protect our intellectual property portfolio;
anticipated liquidity and capital requirements;
anticipated future losses and our ability to continue as a going concern;
expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations;
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, OvaWatch, as well as our Aspira Synergy platform;
expectations regarding our ability to launch new products we develop or license, co-market or acquire new products;
expectations regarding the size of the markets for our products;
expectations regarding reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans;
plans to use each of AbbVie Inc. serum samples and ObsEva S.A. plasma samples in EndoCheck product validation studies as well as procure serum samples from other potential partnerships or studies;
potential plans to pursue clearance designation with the FDA with respect to EndoCheck and OvaWatch;
expected target launch timing for OvaWatch and EndoCheck;
expectations regarding compliance with federal and state laws and regulations relating to billing arrangements conducted in coordination with laboratories;
plans to advocate for legislation and professional society guidelines to broaden access to our products and services;
expectations regarding the impacts resulting from or attributable to the COVID-19 pandemic and actions taken to contain it;
plans regarding discontinuing the Aspira GenetiX product and related genetics testing offerings; and
expectations regarding the results of our academic research agreements.

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, as supplemented by the section entitled “Risk Factors” in this Quarterly Report on Form 10-Q, that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including our ability to continue as a going concern; our ability to comply with Nasdaq’s continued listing requirements; impacts resulting from potential changes to coverage of Ova1 through our Medicare Administrative Carrier for Ova1; impacts resulting from or relating to the COVID-19 pandemic and actions taken to contain it; anticipated use of capital and its effects; our ability to increase the volume of our product sales; failures by third-party payers to reimburse for our products and services or changes to reimbursement rates; our ability to continue

developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform LDTs; our ability to comply with FDA regulations that relate to our products and to obtain any FDA clearance or approval required to develop and commercialize medical devices; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; or our suppliers' ability to comply with FDA requirements for production, marketing and post-market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; in the event that we succeed in commercializing our products outside the United States, the political, economic and other conditions affecting other countries; changes in healthcare policy; our ability to comply with environmental laws; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; our ability to use our net operating loss carryforwards; our ability to use intellectual property; our ability to successfully defend our proprietary technology against third parties; our ability to obtain licenses in the event a third party successfully asserts proprietary rights; the liquidity and trading volume of our common stock; the concentration of ownership of our common stock; our ability to retain key employees; our ability to secure additional capital on acceptable terms to execute our business plan; business interruptions; the effectiveness and availability of our information systems; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; future litigation against us, including infringement of intellectual property and product liability exposure; and additional costs that may be required to make further improvements to our laboratory operations.

Company Overview

Corporate Vision

Our core mission is to transform women's gynecologic health through the development of technology-enabled diagnostic tools, starting with ovarian cancer. We aim to eradicate late-stage detection of ovarian cancer and to ensure that our solutions will meet the needs of women of all ages, races, ethnicities and stages of the disease.

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

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

Growth. In 2022, we have continued to grow Ova1Plus product volume and revenue through our commercial team. In addition, in October 2022, we launched a co-marketing and distribution collaboration with BioReference Health, LLC (formerly known as BioReference Laboratories, Inc.), a subsidiary of OPKO Health, Inc. ("BRL"), as a new channel for volume growth. We aim not only to increase the number of physicians ordering for the first time but also to increase repeat orders from existing physician customers. Positive trends in the tenure of our sales professionals have led to year-over-year volume growth.

Innovation. Innovation is fundamental to the long-term success of any diagnostics company. For Aspira, it starts with the expansion of our ovarian cancer portfolio, which is now branded as OvaSuite. Our first Lab Developed Test ("LDT"), OvaWatch, is a non-invasive ovarian cancer risk assessment for women with adnexal masses with an initial clinical assessment that is either benign or indeterminate. This assay will significantly expand our patient population beyond the population that existed with our current Ova1Plus test. OvaWatch is expected to be launched in the fourth quarter of 2022. The OvaWatch

manuscript, "Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer," has been published online in the Journal of Clinical Oncology Clinical Cancer Informatics.

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

Operational Excellence. We expect to achieve our cash utilization goals for 2022 by focusing on spending that fuels innovation and growth. Since March 1, 2022, we identified redundant or unnecessary roles in our workforce and eliminated approximately 19% of our headcount. The personnel actions we will have taken by the end of the year will reduce base salary costs by more than $3,000,000 in 2023. We plan, however, to continue to hire individuals to fill key roles, especially in commercial and research and development.

Our Business and Products

We currently market and sell the following products and related services: (1) Ova1, a blood test intended as an aid to further assess the likelihood of malignancy in women with an ovarian adnexal mass for which surgery is planned when the physician's independent clinical and radiological evaluation does not indicate malignancy; (2) Overa, a second-generation biomarker reflex test intended to maintain Ova1's high sensitivity while improving specificity; (3) Ova1Plus, a reflex offering which uses Ova1 as the primary test and Overa as a confirmation for Ova1 intermediate range results and leverages the strengths of Ova1's multivariate index assay ("MIA") sensitivity and Overa's (MIA2G) specificity and as a result reduces false elevations by over 40%; and (4) Aspira Synergy, our decentralized testing platform and cloud service for decentralized global access of protein biomarker testing. We continue to make Ova1, Overa, and Ova1Plus, and plan to make 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. Revenue from these sources (in addition to revenue from Aspira GenetiX) is included in the results of operations in total revenue for the nine months ended September 30, 2022.

In 2021, we began entering into decentralized arrangements with large healthcare networks and physician practices for our Aspira Synergy platform. The modules available under Aspira Synergy include our flagship Ova1Plus risk assessment and genetics carrier screening. As described further below, as of September 2022, genetics carrier screening will no longer be available. The Company has entered into four technology transfer agreements since the launch of Aspira Synergy. Two of the agreements are with independent regional laboratories and are in the process of being launched and piloted. One of the agreements is with one of the nation's largest and leading independent women's healthcare groups which has already launched and is contributing to our Ova1Plus volume. The last of the four agreements with Axia Women's Health, which had been intended to deliver genetics carrier screening, was cancelled by the customer in the third quarter of 2022. This cancellation, along with the general deterioration of commercial opportunities in the genetics carrier screening market, has led us to cease providing Aspira GenetiX, including genetics carrier screening, on our Aspira Synergy platform, effective as of September 30, 2022. This is not expected to have a material impact on our revenues in 2022 or in any future periods.

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. 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 lab as a non-invasive blood-based risk assessment test for use in conjunction with clinical assessment and imaging to determine ovarian cancer risk for patients with an adnexal mass who are not yet scheduled for surgery. 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 the commercial phase of the OvaWatch single use risk assessment test, including driving provider adoption, during the fourth quarter of 2022. We believe OvaWatch has the potential to significantly expand the addressable market compared to Ova1Plus. The launch of the serial monitoring test is targeted for the fourth quarter of 2023 following the expected publication of data from the ongoing prospective serial monitoring clinical study.

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

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 comparable sensitivity and specificity when compared to surgical biopsy and/or visualization. We expect that our research collaboration agreement with DFCI, BWH, and Medical University of Lodz will bolster our research and development efforts and scientific resources to accelerate commercialization of our endometriosis product portfolio. Our goal is to launch EndoCheck in the second half of 2023 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 ovarian cancer. It will use genetics, proteins and other modalities to assess the likelihood that a woman has an early-stage gynecological cancer that is not visible using traditional ultrasound methodologies, and thereby to aid in early diagnoses. Our OvaInherit related clinical studies, OvaNex and Ova360, initiated in late 2019 and early 2020, respectively, are focused on developing data to support a diagnostic test for the early detection of ovarian cancer.

We ultimately plan to commercialize OvaSuite and EndoCheck on a global scale. We currently hold CE marks for Ova1 and Overa.

Outside of the United States, there are studies in process in both the Philippines and Israel, which are intended to validate Overa and Ova1 in specific populations. The study occurring in the Philippines includes Aspira's first agreement regarding Aspira Synergy for Overa specimen testing. The first paper from the Philippines study was published in the third quarter of 2022.

We own and operate ASPiRA LABS, based in Austin, Texas, a Clinical Chemistry and Endocrinology Laboratory accredited by the College of American Pathologists, which specializes in applying biomarker-based technologies to address critical needs in the management of gynecologic cancers and disease. ASPiRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based risk assessment to aid in clinical decision making and advance personalized treatment plans. The lab currently performs our Ova1, Overa and additional tumour and hormone 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 billed by the Company being performed exclusively at ASPiRA LABS in Texas, the local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. ASPiRA LABS also bills third-party commercial and other government payers as well as client bill accounts and patients for Ova1.

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

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

Recent Developments

Business and Listing Updates

On August 8, 2022, we entered into a sponsored research agreement with DFCI, BWH, and Medical University of Lodz for the generation of a multi-omic, non-invasive diagnostic aid to identify endometriosis based on circulating microRNAs and proteins. This collaboration is expected to accelerate our development and commercialization of future endometriosis products, such as EndoCheck. Under the terms of the agreement, payments of approximately $1,252,000 have or will become due from us to the counterparties upon the successful completion of deliverables as defined in the agreement in 2022 and 2023 as follows: 68% was paid in August 2022, 15% will become payable upon completion of certain deliverables estimated to occur in the fourth quarter of 2022, and 17% will become payable upon completion of certain deliverables estimated to occur in the second quarter of 2023. As of September 30, 2022 approximately $852,000 has been recorded as expense for the project.

We have prepared an application for a Proprietary Laboratory Analyses code with the American Medical Association for OvaWatch to distinguish it from Ova1Plus with the 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.

On June 1, 2022, we received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying us that, for the preceding 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule"). As provided in the Nasdaq rules, we have 180 calendar days, or until November 28, 2022, to regain compliance with the Minimum Bid Price Rule. We may achieve compliance during this period if the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days. If we fail to regain compliance on or prior to November 28, 2022, we may be eligible for an additional 180-calendar day compliance period, which would extend the deadline until May 27, 2023. There is no assurance that we will be able to regain compliance by the

November 28, 2022 deadline or the additional 180-calendar day extended deadline, and there is no assurance that we will otherwise maintain compliance with this or any of the other Nasdaq continued listing requirements.

Recent Publications

As part of our support of research related to the impact of race and ethnicity on the detection of ovarian cancer, a manuscript arising from clinical research efforts in the Philippines, which we sponsored, was accepted for publication in the *International Journal of Environmental Research and Public Health* in June 2022. The resulting data indicated that Overa exhibited better overall performance in detecting ovarian cancer, regardless of menopausal status, compared to CA-125. The study also showed that Overa had the best overall performance of all individual classifiers, including in some of the most difficult to detect cancer cohorts such as premenopausal women, and early-stage disease.

COVID-19 Pandemic

The COVID-19 pandemic has severely impacted global economic activity, and many countries and many states in the United States reacted to it by instituting quarantines, mandating business and school closures and restricting travel periodically throughout the pandemic. 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 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.

Critical Accounting Policies and Estimates

Our product revenue is generated by performing diagnostic services using our Ova1, Overa or Ova1Plus 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 or Ova1Plus 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 and Ova1Plus 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 September 30, 2022 Compared to Three Months Ended September 30, 2021

The selected summary financial and operating data of the Company for the three months ended September 30, 2022 and 2021 were as follows:

(dollars in thousands)	Three Months Ended September 30, 2022	2021	Increase (Decrease) Amount	%
Revenue:				
Product	$ 2,037	$ 1,617	$ 420	26
Genetics	35	49	(14)	(29)
Total revenue	2,072	1,666	406	24
Cost of revenue:				
Product	875	715	160	22
Genetics	41	202	(161)	(80)
Total cost of revenue	916	917	(1)	(0)
Gross profit	1,156	749	407	54
Operating expenses:				
Research and development	2,157	1,518	639	42
Sales and marketing	3,950	5,083	(1,133)	(22)
General and administrative	4,746	3,839	907	24
Total operating expenses	10,853	10,440	413	4
Loss from operations	(9,697)	(9,691)	(6)	0
Change in fair value of warrant liabilities	5,004	-	5,004	-
Interest income (expense), net	18	(14)	32	229
Other (expense), net	117	(2)	119	5,950
Net loss	$ (4,558)	$ (9,707)	$ 5,149	(53)

Product Revenue. Product revenue was $2,037,000 for the three months ended September 30, 2022, compared to $1,617,000 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 26% product revenue increase is due to an increase in Ova1 test volume compared to the prior year, partially offset by a lower revenue average unit price ("AUP"), which decreased from $378 in the third quarter of 2021 to $369 in the third quarter of 2022.

Medicaid represents approximately 13.6% of volume in the three months ended September 30, 2022, at an AUP of $88. This is compared to 12.0% of volume in the same period in 2021, at an AUP of $94. Our Ova1Plus AUP without Medicaid was $415 for the three months ended September 30, 2022, compared to $410 for the same period in 2021. Product revenue increased 1% sequentially for the third quarter of 2022 as compared to the second quarter of 2022.

The number of product tests performed increased 29% to 5,524 during the three months ended September 30, 2022, compared to 4,281 product tests for the same period in 2021. The number of product tests performed increased 2% sequentially during the third quarter 2022 as compared to the second quarter 2022. These increases are a result of increased access to provider offices and increased investment in our current commercial channel. We expect revenue to continue to increase in 2022 due to our investment in key salesforce hires and strategic product development.

Genetics Revenue. Genetics revenue was $36,000 for the three months ended September 30, 2022, compared to $49,000 for the same period in 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 27% genetics revenue decrease is primarily due to decreased volumes and decreased AUP as compared to the same period in 2021. The Company has discontinued offering genetics testing effective September 30, 2022.

Cost of Revenue – Product. Cost of product revenue was $875,000 for the three months ended September 30, 2022, compared to $715,000 for the same period in 2021, representing an increase of $160,000, or 22%, due primarily to increased personnel costs, lab supply costs, and software license fees resulting from the increase in tests performed compared to the prior year. The cost of revenue increased at a rate lower than the revenue percent increased as we leveraged our fixed laboratory costs.

Cost of Revenue – Genetics. Cost of genetics revenue, which consisted primarily of personnel costs and consulting expense related to the launch of Aspira GenetiX, was $41,000 for the three months ended September 30, 2022, compared to $202,000 for the same period in 2021. The decrease in cost was due to a decrease of $104,000 in personnel costs, and a decrease in volume of tests performed as compared to the same period in 2021. The Company has discontinued the genetics testing offering effective September 30, 2022.

Gross Profit Margin. Gross profit margin for Ova1Plus remained relatively flat at 57.0% for the three months ended September 30, 2022, and 56% 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 September 30, 2022 increased by $639,000, or 42%, compared to the same period in 2021. This increase was primarily due to clinical validity and product development costs related to OvaWatch in addition to approximately $852,000 of costs related to our collaboration with DFCI, BWH and Medical University of Lodz, which relates to our endometriosis product portfolio, partially offset by a decrease in clinical trial expenses of $134,000 and a decrease of recruiting expenses of $112,000. We expect research and development expenses to increase in 2022, sequentially as well as relative to 2021, as a result of increased projects, clinical studies and our research collaboration agreements.

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 and Ova1Plus. 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 September 30, 2022 decreased by $1,133,000, or 22%, compared to the same period in 2021. This decrease was primarily due to decreased personnel in the marketing area, decreases in recruiting expenses and decreases in external marketing expenses. We expect sales and marketing expenses to modestly increase sequentially in 2022 as we prepare to launch OvaWatch.

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 September 30, 2022 increased by $907,000, or 24%, compared to the same period in 2021. This increase was primarily due to issuance costs associated with issuance of warrants of $1,117,000 (see Note 2 to the unaudited condensed consolidated financial statements), personnel expenses of $491,000, partially offset by decreased consulting and legal expenses of $571,000 and $102,000, respectively. We expect general and administrative expenses to remain relatively flat sequentially in 2022.

Change in fair value of warrant liabilities. The fair values of the warrants as of August 22, 2022, the issuance date, and September 30, 2022 were $7,752,000 and $2,748,000, respectively, for a net change in fair value of $5,004,000.

Results of Operations – Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

The selected summary financial and operating data of the Company for the nine months ended September 30, 2022 and 2021 were as follows:

(dollars in thousands)	Nine Months Ended September 30, 2022	2021	Increase (Decrease) Amount	%
Revenue:				
Product	$ 5,890	$ 4,753	$ 1,137	24
Genetics	141	208	(67)	(32)
Total revenue	6,031	4,961	1,070	22
Cost of revenue:				
Product	2,768	2,209	559	25
Genetics	180	704	(524)	(74)
Total cost of revenue	2,948	2,913	35	1
Gross profit	3,083	2,048	1,035	51
Operating expenses:				
Research and development	4,915	3,861	1,054	27
Sales and marketing	12,027	12,209	(182)	(1)
General and administrative	13,305	9,627	3,678	38
Total operating expenses	30,247	25,697	4,550	18
Loss from operations	(27,164)	(23,649)	(3,515)	15
Change in fair value of warrant liabilities	5,004	-	5,004	-
Interest (expense), net	(10)	(35)	25	(71)
Other income, net	101	983	(882)	(90)
Net loss	$ (22,069)	$ (22,701)	$ 632	(3)

Product Revenue. Product revenue was $5,890,000 for the nine months ended September 30, 2022, compared to $4,753,000 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 24% product revenue increase is primarily due to an increase in Ova1 test volume compared to the prior year, partially offset by a decrease in AUP, which decreased from $377 for the nine months ended September 30, 2021 to $373 in the same period of 2022.

Medicaid represents approximately 12.4% of volume in the nine months ended September 30, 2022, at an AUP of $89. This is compared to 11.8% of volume for the same period in 2021, at an AUP of $91. Our Ova1Plus AUP without Medicaid was $416 for the nine months ended September 30, 2022, compared to $413 for the same period in 2021.

The number of product tests performed increased 25% to 15,781 during the nine months ended September 30, 2022, compared to 12,609 product tests for the same period in 2021. This increase was due to increased access to provider offices and focused investment in our current commercial channel.

Genetics Revenue. Genetics revenue was $142,000 for the nine months ended September 30, 2022, compared to $208,000 for the same period in 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 32% genetics revenue decrease is primarily due to decreased volumes as compared to the same period in 2021, in addition to the AUP decreased to $420 from $478 from the same period in 2021. The Company has discontinued the genetics testing offering effective September 30, 2022.

Cost of Revenue – Product. Cost of product revenue was $2,768,000 for the nine months ended September 30, 2022, compared to $2,209,000 for the same period in 2021, representing an increase of $559,000, or 25%, due primarily to proportionate increases in personnel costs, lab supply costs, and software license fees resulting from 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 $180,000 for the nine months ended September 30, 2022, compared to $704,000 for the same period in 2021. The decrease in cost was due to a decrease of $322,000 in personnel costs and a decrease in volume of tests performed as compared to the same period in 2021. The Company has discontinued the genetics testing offering effective September 30, 2022.

Gross Profit Margin. Gross profit margin for Ova1Plus decreased slightly to 52.9% for the nine months ended September 30, 2022, compared to 54.4% for the same period in 2021. This decrease was primarily related to increased personnel costs, lab supply costs, and software license fees.

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 nine months ended September 30, 2022 increased by $1,054,000, or 27%, compared to the same period in 2021. This increase was primarily due to clinical validity, product development costs related to OvaWatch, in addition to approximately $852,000 of costs related to our collaboration with DFCI, BWH and Medical University of Lodz, which relates to our endometriosis product portfolio, increases in employment related expenses of $283,000, partially offset by a decrease in clinical trial expenses of $118,000. In addition, there was severance paid in relation to our commercial reorganization and job eliminations of $152,000. We expect research and development expenses to increase in 2022, sequentially as well as 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 and Ova1Plus. 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 nine months ended September 30, 2022 decreased by $182,000, or 1%, compared to the same period in 2021. This decrease was primarily due to decreased recruiting and marketing expense, partially offset by increased personnel, severance paid in relation to our reorganization, commissions, sales meetings and travel and entertainment costs. We expect sales and marketing expenses to increase sequentially in 2022, 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 2022 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 nine months ended September 30, 2022 increased by $3,678,000, or 38%, compared to the same period in 2021. This increase was primarily due to issuance costs associated with issuance of warrants of $1,117,000 (see Note 2 to the unaudited condensed consolidated financial statements), increased personnel related expenses of $2,803,000 and legal fees of $220,000. Severance paid to general and administrative-related personnel was immaterial. We expect general and administrative expenses to remain relatively flat sequentially in 2022.

Change in fair value of warrant liabilities. The fair values of the warrants as of August 22, 2022, the issuance date, and September 30, 2022 were $7,752,000 and $2,748,000, respectively, for a net change in fair value of $5,004,000.

Liquidity and Capital Resources

We plan to continue to expend resources selling and marketing Ova1, Overa and Ova1Plus and developing additional diagnostic tests and service capabilities. We plan to launch our next generation ovarian cancer risk assessment test, OvaWatch, in the fourth quarter of 2022.

We have incurred significant net losses and negative cash flows from operations since inception, and as a result have an accumulated deficit of approximately $493,797,000 as of September 30, 2022. We also expect to incur a net loss and negative cash flows from operations for 2022. Working capital levels may not be sufficient to fund operations as currently planned through the next twelve months, absent a significant increase in revenue over historic revenue or additional financing. Given the above conditions, there is substantial doubt about our ability to continue as a going concern.

We expect to raise capital through sources that may include public or private equity offerings, debt financings, the exercise of common stock warrants, collaborations, licensing arrangements, grants and government funding and strategic alliances. However, additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may not be able to continue sales and marketing, research and development, or other operations on the scope or scale of current activity, and that could have a material adverse effect on our business, results of operations and financial condition.

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

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

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.

As discussed in Note 3 to the condensed consolidated financial statements, on August 22, 2022, the Company completed a public offering (the "2022 Offering") resulting in net proceeds of approximately $7,704,000, after deducting underwriting discounts and offering expenses of $1,296,000.

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, granted two of the primary investors in that offering the right to participate in any future equity offerings by the Company on the same price and terms as other investors. In addition, the stockholders agreement prohibits us from taking certain material actions without the consent of at least one of the two primary investors in that offering. These material actions include:

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

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

As mentioned, 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 September 30, 2022 we had an accumulated deficit of ($493,797,000) and stockholders' equity of $11,178,000. As of September 30, 2022, we had $20,551,000 of cash and cash equivalents (excluding restricted cash of $250,000), $7,297,000 of current liabilities, and working capital of $15,679,000. 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.

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 and Ova1Plus 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.

The first quarter of 2022 had higher, non-recurring costs, including personnel costs associated with our commercial reorganization, in addition to costs related to our annual performance plan payout. In the third quarter of 2022, the impact of our operational excellence strategic initiatives began, most notably with respect to reduced consulting costs as we focused on innovation, and specifically on OvaWatch and EndoCheck. We also enhanced our sales and marketing in preparation for the BRL collaboration and the launch of OvaWatch. We expect to see

sequential improvement in net cash utilization in the fourth quarter of 2022 compared to the third quarter as we do not plan to incur one-time research and collaboration costs, which was incurred in the third quarter of 2022, and as we start to see the impact of our anticipated top line growth.

Net cash used in operating activities was $25,109,000 for the nine months ended September 30, 2022, resulting primarily from the net loss reported of $22,069,000, which includes non-cash expenses in the amount of $5,004,000 relating to a change in warrant fair value (see Note 2 to the unaudited condensed consolidated financial statements), $1,994,000 related to stock compensation expense and $195,000 related to depreciation and amortization, offset by changes in prepaid expense and other assets of $694,000 and changes in accounts payable, accrued liabilities and other liabilities of $653,000, and changes in accounts receivable of $174,000 and inventory of $106,000.

Net cash used in operating activities was $19,746,000 for the nine months ended September 30, 2021, resulting primarily from the net loss reported of $22,701,000, which includes non-cash items such as stock compensation expense of $2,949,000, PPP loan forgiveness of $1,006,000 and depreciation and amortization of $238,000, offset by changes in prepaid expense and other assets of $262,000 and changes in accounts payable, accrued liabilities and other liabilities of $821,000, partially offset by changes in accounts receivable of $238,000 and inventory of $107,000.

Net cash used in investing activities was $158,000 and $154,000 for the nine months ended September 30, 2022 and 2021, respectively, which consisted of property and equipment purchases.

Net cash provided by financing activities was $8,638,000 for the nine months ended September 30, 2022, stemming primarily from the 2022 Offering, resulting in net proceeds of $8,821,000, after deducting allocated underwriting discounts and offering expenses of $179,000, in addition to principal payments on the DECD loan. Net cash provided by financing activities was $48,389,000 for the nine months ended September 30, 2021, which resulted primarily from the 2021 Offering, resulting in net proceeds to the Company of approximately $47,858,000, after deducting underwriting discounts and offering expenses of $378,000. There was a change in estimate in the third quarter of 2021 in the amount of $137,000 relating to an expense reversal of offering costs.

Based on the available objective evidence, we believe it is more likely than not that net deferred tax assets will not be fully realizable. Accordingly, we have provided a full valuation allowance against the Company's net deferred tax assets. Therefore, there was no deferred income tax expense or benefit for the period.

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.

Our ability to use the Company's net operating loss and credit carryforwards to offset future taxable income is restricted due to ownership change limitations that have occurred in the past, as required by Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state provisions. Net operating losses which are limited from offsetting any future taxable income under Section 382 are not included in the gross deferred tax assets. 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.

Our unrecognized tax benefits attributable to research and development credits will increase during the period for tax positions taken during the year and will/ decrease for expiration of a portion of the carryforwards during the period.

Off-Balance Sheet Arrangements

As of September 30, 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 September 30, 2022. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 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 September 30, 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

Except as set forth below, 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 below and 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.

Failure to meet Nasdaq's continued listing requirements could result in the delisting of Aspira common stock, negatively impact the price of Aspira common stock and negatively impact our ability to raise additional capital.

On June 1, 2022, we received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market stating that, for the preceding 30 consecutive business days, the closing bid price for Aspira common stock was below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule"). As provided in the Nasdaq rules, we have 180 calendar days, or until November 28, 2022, to regain compliance with the Minimum Bid Price Rule. We may achieve compliance during this period if the closing bid price of Aspira common stock is at least $1.00 per share for a minimum of 10 consecutive business days. If we fail to regain compliance on or prior to November 28, 2022, we may be eligible for an additional 180-calendar day compliance period, which would extend the deadline until May 27, 2023. There is no assurance that we will be able to regain compliance by the November 28, 2022 initial deadline or any extension thereof, and there is no assurance that we will otherwise maintain compliance with any of the other Nasdaq listing requirements.

If we fail to comply with Nasdaq's continued listing requirements, Aspira common stock will be subject to delisting. If that were to occur, Aspira common stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell Aspira securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in Aspira common stock. This would adversely affect the ability of investors to trade Aspira securities and would adversely affect the value and liquidity of Aspira common stock, as well as negatively impact our ability to raise additional capital. These factors could contribute to lower prices and larger spreads in the bid and ask prices for Aspira common stock. If we seek to implement a reverse stock split in order to remain listed on The Nasdaq Capital Market, the announcement or implementation of such a reverse stock split could negatively affect the price of Aspira common stock.

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

We have incurred significant losses and negative cash flows from operations since inception and have an accumulated deficit of nearly $494 million as of the end of the period covered by this report. We also expect to incur a net loss and negative cash flows from operations in 2022. Given these conditions, there is a risk that this may adversely impact our stock price, and therefore substantial doubt about our ability to continue as a going concern.

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

Failure to continue coverage of Ova1 through the Company's Medicare Administrative Carrier for Ova1 (Novitas).

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

We may need to sell additional shares of our common stock or other securities in the future to meet our capital requirements, which could cause significant dilution.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of the issuance of common stock in public or private equity offerings, debt financings, exercise of common stock warrants, collaborations, licensing arrangements, grants and government funding and strategic alliances. As discussed in "Risks Related to our Business and Industry," our management believes the successful achievement of our business objectives will require additional financing through one of these avenues. To the extent that we raise additional capital through the sale of equity or convertible debt, such financing may be dilutive to stockholders. Debt financing, if available, may involve restrictive covenants and potential dilution to stockholders. Furthermore, a perception that future sales of our common stock in the public market are likely to occur could affect prevailing trading prices of our common stock.

As of September 30, 2022, we had 124,445,639 shares of our common stock outstanding and 3,531,486 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 9,873,424 shares of our common stock that were subject to outstanding options. In addition, as of September 30, 2022, warrants to purchase 12,000,000 shares of our common stock were outstanding. These warrants are exercisable at the election of the holders thereof, in accordance with the terms of the related Form of Warrant, at an average exercise price of $0.88 per share.

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

ITEM 5. OTHER INFORMATION

On November 5, 2022, Robert Beechey, the Chief Financial Officer, principal financial officer and principal accounting officer of the Company, notified the Company that he will resign from these roles with the Company effective November 30, 2022. Effective December 1, 2022, Mr. Beechey will transition to a consulting role at the Company, pursuant to the Consulting Agreement, dated November 10, 2022 (the "Consulting Agreement"), between Mr. Beechey and the Company.

Under the Consulting Agreement, Mr. Beechey will provide the Company with accounting and finance services, as needed, including, without limitation, assistance in connection with the transition of financial leadership. Under the Consulting Agreement, Mr. Beechey will be entitled to receive $20,000 per month for up to 40 hours of service per month through May 31, 2023. The Consulting Agreement also provides for a 12-month non-solicitation period following the termination or expiration of the Consulting Agreement. The Consulting Agreement expires on May 31, 2023.

In addition, Mr. Beechey and the Company entered into a Separation Agreement, dated November 10, 2022 (the "Separation Agreement"), that provides that, in consideration for the release of all claims against the Company, (i) options granted during Mr. Beechey's service to the Company, including during the time period during which he is performing services for the Company under the Consulting Agreement, will accrue and vest through May 31, 2023 and (ii) Mr. Beechey will have until March 31, 2024 to exercise any vested options.

The foregoing description of terms of the Consulting Agreement and the Separation Agreement is qualified in its entirety by reference to the complete agreements, copies of which are attached as Exhibit 10.2 and Exhibit 10.3 to this Quarterly Report on Form 10-Q.

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 Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated January 22, 2010	8-K	000-31617	3.1	January 25, 2010	
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation, effective June 19, 2014	10-Q	001-34810	3.2	August 14, 2014	
3.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated June 11, 2020	8-K	001-34810	3.1	June 11, 2020	
3.4	Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock	8-K	001-34810	4.1	April 17, 2018	
3.5	Amended and Restated Bylaws of Aspira Women's Health Inc., effective February 23, 2022	8-K	001-34810	3.1	February 28, 2022	
4.1	Form of Warrant, issued on August 22, 2022	8-K	001-34810	4.1	August 22, 2022	
10.1	First Amendment to Employment Agreement between Aspira Women's Health Inc. and Robert Beechey dated September 20, 2022 #					√
10.2	Separation Agreement and Release between Aspira Women's Health Inc. and Robert Beechey dated November 10, 2022 #					√
10.3	Consulting Agreement between Aspira Women's Health Inc. and Robert Beechey dated November 10, 2022 #					√
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					√√
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL")					√
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					√

√ Filed herewith
√√ Furnished herewith
Management contract or compensatory plan or arrangement.

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: November 10, 2022

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

Date: November 10, 2022

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