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 June 30, 2021

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 August 9, 2021, the registrant had 112,067,034 shares of common stock, par value $0.001 per share, outstanding.

ASPIRA WOMEN'S HEALTH INC.

FORM 10-Q

For the Quarter Ended June 30, 2021

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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)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 52,993	$ 16,631
Accounts receivable	1,073	865
Prepaid expenses and other current assets	740	1,077
Inventories	101	30
Total current assets	54,907	18,603
Property and equipment, net	546	583
Right-of-use assets	376	406
Other assets	-	13
Total assets	$ 55,829	$ 19,605
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,436	$ 1,103
Accrued liabilities	3,900	3,618
Current portion long-term debt	199	645
Short-term debt	204	611
Lease liability	52	23
Total current liabilities	5,791	6,000
Non-current liabilities:		
Long-term debt	2,818	3,477
Lease liability	382	409
Total liabilities	8,991	9,886
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at June 30, 2021 and December 31, 2020; 112,058,034 and 104,619,876 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	112	105
Additional paid-in capital	499,786	449,680
Accumulated deficit	(453,060)	(440,066)
Total stockholders' equity	46,838	9,719
Total liabilities and stockholders' equity	$ 55,829	$ 19,605

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product	$ 1,718	$ 726	$ 3,134	$ 1,911
Genetics	79	17	159	42
Service	2	3	2	13
Total revenue	1,799	746	3,295	1,966
Cost of revenue[1]:				
Product	825	458	1,473	1,123
Genetics	278	131	523	261
Service	-	4	-	9
Total cost of revenue	1,103	593	1,996	1,393
Gross profit	696	153	1,299	573
Operating expenses:				
Research and development[2]	1,471	380	2,343	775
Sales and marketing[3]	4,018	1,733	7,126	3,848
General and administrative[4]	3,279	1,866	5,788	3,576
Total operating expenses	8,768	3,979	15,257	8,199
Loss from operations	(8,072)	(3,826)	(13,958)	(7,626)
Interest income (expense), net	3	1	(21)	9
Other income (expense), net	995	(6)	985	80
Net loss	$ (7,074)	$ (3,831)	$ (12,994)	$ (7,537)
Net loss per share - basic and diluted	$ (0.06)	$ (0.04)	$ (0.12)	$ (0.08)
Weighted average common shares used to compute basic and diluted net loss per common share	111,958,928	98,123,789	110,311,666	97,707,904
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$ 53	$ 28	$ 87	$ 53
(2) Research and development	94	1	120	1
(3) Sales and marketing	337	43	476	85
(4) General and administrative	798	369	1,088	571

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	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 of $0.5 million	6,900,000	7	47,713	-	47,720
Stock compensation charge	-	-	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 compensation charge	-	-	1,015	-	1,015
Balance at June 30, 2021	112,058,034	$ 112	$ 499,786	$ (453,060)	$ 46,838

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2019	97,286,157	$ 97	$ 430,802	$ (422,161)	$ 8,738
Net loss	-	-	-	(3,706)	(3,706)
Common stock issued in conjunction with exercise of stock options	2,500	-	1	-	1
Stock compensation charge	-	-	269	-	269
Balance at March 31, 2020	97,288,657	$ 97	$ 431,072	$ (425,867)	$ 5,302
Net loss	-	-	-	(3,831)	(3,831)
Common stock issued in conjunction with exercise of stock options	247,625	-	295	-	295
Common stock issued for restricted stock awards	178,470	-	121	-	121
Common stock issued in conjunction with warrant exercises	2,810,338	4	5,056	-	5,060
Stock compensation charge	-	-	320	-	320
Balance at June 30, 2020	100,525,090	$ 101	$ 436,864	$ (429,698)	$ 7,267

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)

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (12,994)	$ (7,537)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	32	-
Depreciation and amortization	172	114
Stock-based compensation expense	1,771	710
Loss on sale and disposal of property and equipment	1	2
Forgiveness of PPP loan	(1,006)	-
Changes in operating assets and liabilities:		
Accounts receivable	(208)	105
Prepaid expenses and other assets	350	(99)
Inventories	(71)	(41)
Accounts payable, accrued liabilities and other liabilities	208	(165)
Net cash used in operating activities	(11,745)	(6,911)
Cash flows from investing activities:		
Purchase of property and equipment	(136)	(123)
Net cash used in investing activities	(136)	(123)
Cash flows from financing activities:		
Principal repayment of DECD loan	(99)	(96)
Proceeds from issuance of common stock from exercise of stock options	621	296
Proceeds from PPP loan	-	1,006
Proceeds from exercise of warrants	-	5,060
Proceeds from public offering	48,236	-
Payment of offering costs for public offering	(515)	-
Net cash provided by financing activities	48,243	6,266
Net increase (decrease) in cash and cash equivalents	36,362	(768)
Cash and cash equivalents, beginning of period	16,631	11,703
Cash and cash equivalents, end of period	$ 52,993	$ 10,935
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	38	18
Supplemental disclosure of noncash investing and financing activities:		
Net (decrease) increase in right-of-use assets	(30)	11

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 designed to, in addition to a physician's clinical assessment of a woman with a pelvic mass, identify women who are at high-risk of having a malignant ovarian tumor prior to planned surgery; (2) OVERA, a second-generation biomarker panel intended to maintain OVA1's high sensitivity while improving specificity; (3) OVA1plus, a reflex offering, which uses OVA1 and OVERA as a confirmation for OVA1 intermediate range results and leverages the strengths of OVA1's Multivariate Index Assay ("MIA") sensitivity and OVERA's (MIA2G) specificity and as a result reduces false elevations by over 40%; (4) Aspira GenetiX, a genetic test for gynecological cancer risk, with a core focus on female cancers, including breast, ovarian, endometrial, uterine and cervical cancers; and (5) Aspira Synergy, the Company's new decentralized platform and cloud service technology. Through June 30, 2021, the Company's product and related services revenue was limited to revenue generated by sales of OVA1, OVA1plus and Aspira GenetiX. The Company sells OVA1 and OVA1plus through Aspira's wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, Aspira Labs, Inc. ("ASPiRA LABS"). In 2021, the Company began to enter into decentralized arrangements with large healthcare networks and large practices for its Aspira Synergy product. In the second quarter of 2021, the Company secured its first decentralized arrangement using the Aspira Synergy platform with one of the largest women's care super groups in the U.S.

Liquidity

The Company has incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately $453,060,000. The Company also expects to incur a net loss and negative cash flows from operations for 2021.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. The novel coronavirus has since spread to over 100 countries, including every state in the United States. In March 2020, the World Health Organization declared COVID-19, the disease caused by the novel coronavirus, a pandemic, and the United States declared a national emergency with respect to the coronavirus outbreak. This outbreak has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. In addition, many conventions and industry conferences have been canceled.

As a result of the COVID-19 pandemic and actions taken to contain it, the Company's test volume, and resulting revenue, decreased significantly in late March and the full month of April 2020 as fewer patients visited their physicians and elective surgeries were postponed as a result of closures. The Company saw some increases in its test volume towards the latter half of the second quarter and in the third quarter of 2020, and test volume trended back to pre-COVID-19 levels during the late third quarter 2020. In order to reduce the impact of limitations on visiting physician offices due to closures and quarantines, the Company implemented other mechanisms for reaching physicians such as virtual sales representative meetings and increased digital sales and marketing. Enrollment for future studies has been slower than originally planned due to the impact of current closures for some states. The full impact of the COVID-19 pandemic continues to evolve as of the date of this filing. As a result, the Company is unable to estimate the extent of the impact of the COVID-19 pandemic on its operations or liquidity.

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

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

On April 10, 2020, the Company received a stimulus check of approximately $89,000 from the U.S. Department of Health and Human Services pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act").

As discussed in Note 3, on May 1, 2020, the Company obtained a loan (the "PPP Loan") from BBVA USA in the aggregate amount of $1,005,767, pursuant to the Paycheck Protection Program (the "PPP"), which was established under the CARES Act, as administered by the U.S. Small Business Administration (the "SBA").

As discussed in Note 4, during June 2020, all of the warrants from the Company's 2017 private placement were exercised. The Company received $5,058,608 in aggregate proceeds from the exercise of the warrants.

As discussed in Note 4, on July 20, 2020, the Company completed a private placement of Aspira common stock, par value $0.001 per share, for net proceeds of $10,600,000, after deducting expenses related to the private placement.

As discussed in Note 4, on February 8, 2021, the Company completed a public offering (the "2021 Offering") resulting in net proceeds of approximately $47,700,000, after deducting underwriting discounts and offering expenses.

As discussed in Note 3, in March 2021, the Company applied for forgiveness of the PPP Loan, and, effective May 27, 2021, the SBA confirmed the waiver of the Company's repayment of the PPP Loan. The Company remains subject to an audit of the PPP loan. The Company recognized a gain on forgiveness of debt of $1,005,767, which is included in other income in the condensed consolidated statements of operations, and reduced long- and short-term indebtedness by the same amount.

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 footnotes 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, 2020 included in this report has been derived from the audited consolidated financial statements at that date but does not include all the information and footnotes 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, 2020

included in Aspira's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 31, 2021 (the "2020 Annual Report").

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.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period presentation with no material effect on the consolidated financial statements.

Significant Accounting and Reporting 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 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 June 30, 2021, there were no adjustments to estimates of variable consideration to derecognize revenue for services provided in a prior period. There were no impairment losses on accounts receivable recorded during the periods ended June 30, 2021 and 2020.

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

Service Revenue - The Company's service revenue was generated by performing in vitro diagnostic ("IVD") trial services for third-party customers. Measurement of progress on contracts with customers was generally based on the input measurement of cost incurred relative to the total expected costs to satisfy the performance obligation. The Company does not expect to have any significant service revenue going forward, as it largely wound down performing the ASPiRA IVD, Inc. ("ASPiRA IVD") trial services in the fourth quarter of 2019. During 2020 and 2021, the Company's service revenue was limited to the fulfillment of one legacy IVD contract.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("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. The ASU 2016-13 is scheduled to be effective in 2023 for smaller reporting companies. The Company is currently assessing the impact of this standard on its consolidated financial statements.

2. AGREEMENTS WITH QUEST DIAGNOSTICS INCORPORATED

In March 2015, the Company reached an agreement with Quest Diagnostics, Inc. ("Quest Diagnostics"). Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Aspira's wholly-owned subsidiary, ASPiRA LABS, as of August 2015. Pursuant to this agreement, as amended as of March 11, 2020, Quest Diagnostics has continued to provide blood draw and logistics support by transporting specimens to ASPiRA LABS for testing in exchange for a market value fee. The purpose of the 2020 amendment was to extend the term of the Testing and Services Agreement from March 11, 2019 to March 11, 2023 and for the Company to pay an annual fee of $75,000 for the services of a part-time Quest Diagnostics project manager.

3. COMMITMENTS AND CONTINGENCIES

Coronavirus Aid, Relief, and Economic Security (CARES) Act and PPP Loan

On May 1, 2020, the Company obtained the PPP Loan from BBVA USA in the aggregate amount of $1,005,767. The application for these funds required the Company to, in good faith, certify that the described economic uncertainty at the time made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to consider its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that was not significantly detrimental to the business. Under the terms of the CARES Act and the PPP Loan, all or a portion of the principal amount of the PPP Loan was subject to forgiveness so long as, over the 24-week period following the Company's receipt of the proceeds of the PPP Loan, the Company used those proceeds for payroll costs, rent, utility costs or the maintenance of employee and compensation levels. The PPP Loan, which was granted pursuant to a promissory note, was set to mature on May 1, 2022. The Company applied for forgiveness of the PPP Loan in March 2021, and, effective May 27, 2021, the SBA confirmed the waiver of the Company's repayment of the PPP Loan. The Company recognized a gain on forgiveness of debt of $1,005,767, which is included in other income in the condensed consolidated statements of operations, and reduced long- and short-term indebtedness by the same amount. The Company remains subject to an audit of the PPP loan.

Development Loan

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

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

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

Long-term debt consisted of the following:

(in thousands)	June 30, 2021	December 31, 2020
DECD loan, net of issuance costs	$ 3,017	$ 3,116
PPP loan	-	1,006
Total debt	3,017	4,122
Less: Current portion, net of issuance costs	(199)	(645)
Total long-term debt, net of issuance costs	$ 2,818	$ 3,477

As of June 30, 2021, the annual amounts of future minimum principal payments due under certain of the Company's contractual obligations are shown in the table below. Debt issuance costs for the DECD loan were $17,000. The insurance promissory note of $204,000, as described below, is not included in the table, as the insurance promissory note is cancellable.

	Payments Due by Period						
(in thousands)	Total	2021	2022	2023	2024	2025	Thereafter
DECD Loan	$ 3,034	$ 101	$ 204	$ 406	$ 452	$ 461	$ 1,410
Total	$ 3,034	$ 101	$ 204	$ 406	$ 452	$ 461	$ 1,410

Insurance Notes

During 2020 and 2019, the Company entered into insurance promissory notes for the payment of insurance premiums at an interest rate of 3.88% and 4.49% respectively, with an aggregate principal amount outstanding of approximately $204,000 and $611,000 as of June 30, 2021 and December 31, 2020, respectively. The amount outstanding could be substantially offset by the cancellation of the related insurance coverage which is classified in prepaid insurance. These notes are payable in ten monthly installments with maturity dates of October 1, 2021 and October 1, 2020, respectively.

Operating Leases

The Company leases facilities to support its business of discovering, developing and commercializing diagnostic tests in the fields of gynecologic disease. The Company's principal facility, including the CLIA laboratory used by ASPiRA LABS, is located in Austin, Texas, and the CLIA laboratory used for research and development services is located in Trumbull, Connecticut. In October 2020, the Company renewed the Austin, Texas lease for an additional one year. The Company's renewed lease expires on January 31, 2022, with no automatic renewal or renewal option.

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

The expense associated with these operating leases for the three and six months ended June 30, 2021 and 2020 is shown in the table below (in thousands).

		Three Months Ended June, 30	
Lease Cost	**Classification**	**2021**	**2020**
Operating rent expense			
	Cost of revenue	$ 19	$ 18
	Research and development	13	13
	Sales and marketing	11	4
	General and administrative	21	13
Variable rent expense			
	Cost of revenue	$ 1	$ 1
	Research and development	-	-
	Sales and marketing	11	11
	General and administrative	13	13

		Six Months Ended June, 30	
Lease Cost	**Classification**	**2021**	**2020**
Operating rent expense			
	Cost of revenue	$ 38	$ 33
	Research and development	26	24
	Sales and marketing	22	10
	General and administrative	42	27
Variable rent expense			
	Cost of revenue	$ 2	$ 4
	Research and development	-	1
	Sales and marketing	23	22
	General and administrative	26	27

Based on the Company's leases as of June 30, 2021, the table below sets forth the approximate future lease payments related to operating leases with initial terms of one year or more (in thousands).

2021	$ 45
2022	95
2023	106
2024	116
2025	123
2026	64
Total Operating Lease Payments	549
Less: Interest	(115)
Present Value of Lease Liabilities	$ 434

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

Weighted-average remaining lease term (in years)	5.0
Weighted-average discount rate	9.35%

Non-cancelable Royalty Obligations

The Company is a party to an amended research collaboration agreement with The Johns Hopkins University School of Medicine under which the Company licenses certain of its intellectual property directed at the discovery and validation of biomarkers in human subjects, including but not limited to clinical application of biomarkers in the understanding, diagnosis and management of human disease. Under the terms of the amended research collaboration agreement, Aspira is required to pay the greater of 4% royalties on net sales of diagnostic tests using the assigned patents or annual minimum royalties of $57,500. Royalty expense for the three months ended June 30, 2021 and 2020 totaled $69,000 and $30,000, respectively, and royalty expense for the six months ended June 30, 2021 and 2020 totaled $126,000 and $76,000, respectively, as recorded in cost of revenue in the condensed consolidated statements of operations.

Contingent Liabilities

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

4. STOCKHOLDERS' EQUITY

2020 Exercise of Warrants

On February 17, 2017, the Company issued certain warrants to purchase up to an aggregate of 2,810,338 shares of Aspira common stock at an exercise price of $1.80 per share in connection with a February 2017 private placement of Aspira common stock. The warrants were initially sold at a price of $0.125 per share of common stock underlying the warrants.

On June 1, 2020, following the 20th consecutive trading day for which the closing price per share of Aspira common stock, as reported on the Nasdaq stock market, exceeded the exercise price, the Company sent notice to the investors holding such warrants accelerating the expiration date of the warrants, in accordance with the terms thereof. Pursuant to the terms of the warrants, any portion of the warrants not exercised prior to such accelerated expiration date would become void and of no value.

As of June 9, 2020, all of the warrants were exercised. The Company issued 2,810,338 shares of Aspira common stock and received $5,060,000 in aggregate proceeds from the exercise of the warrants. As of the date of the issuance of these financial statements, there are no outstanding warrants for the purchase of Aspira common stock.

2020 Private Placement

On July 20, 2020, the Company completed a private placement pursuant to which certain investors purchased 3,150,000 shares of Aspira common stock at a price of $3.50 per share. Net proceeds of the private placement were $10.6 million, after deducting expenses related to the private placement of $384,000. The sale of common stock qualified for equity treatment under GAAP.

2021 Public Offering

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

Under the 2021 Underwriting Agreement, the Company granted the 2021 Underwriters an option to purchase up to an additional 900,000 shares of Aspira common stock at the public offering price, less the underwriting discount of $0.4875 per share. On February 5, 2021, the 2021 Underwriters notified the Company that they were exercising this option in connection with the closing of the 2021 Offering. The 2021 Offering, including the additional 900,000 shares of Aspira common stock, closed on February 8, 2021 and resulted in net proceeds to the Company of approximately $47.7 million, after deducting underwriting discounts and offering expenses.

2019 Stock Incentive Plan

At the Company's 2019 annual meeting of stockholders, the Company's stockholders approved the Vermillion, Inc. 2019 Stock Incentive Plan (the "2019 Plan"). The purposes of the 2019 Plan are (i) to align the interests of the Company's stockholders and recipients of awards under the 2019 Plan by increasing the proprietary interest of such recipients in the Company's growth and success; (ii) to advance the interests of the Company by attracting and retaining non-employee directors, officers, other employees, consultants, independent contractors and agents; and (iii) to motivate such persons to act in the long-term best interests of the Company and its stockholders. The 2019 Plan allows the Company to grant stock options, stock appreciation rights, restricted stock, restricted stock units and performance awards to participants.

Subject to the terms and conditions of the 2019 Plan, the initial number of shares authorized for grants under the 2019 Plan is 10,492,283. To the extent an equity award granted under the 2019 Plan expires or otherwise terminates without having been exercised or paid in full, or is settled in cash, the shares of common stock subject to such award will become available for future grant under the 2019 Plan. As of June 30, 2021, 10,244,649 shares of Aspira common stock were subject to outstanding stock options, and 28,136 shares of Aspira common stock were subject to unvested restricted stock awards and a total of 3,828,216 shares of Aspira common stock were reserved for issuance under the 2019 Plan.

Stock-Based Compensation

During the three months ended March 31, 2021, the Company granted the following awards under the 2019 Plan:

Grant Date	Number of Shares	Type of Award	Exercise Price / Share	Fair Value / Share
1/28/2021	262,000	Options	$ 7.79	$ 4.95
3/19/2021	1,971,912	Options	$ 7.40	$ 4.71
3/19/2021	350,000	Performance Options	$ 7.40	$ 4.71
3/19/2021	75,988	Restricted Stock Units	$ -	$ -
	2,659,900			

During the three months ended June 30, 2021, the Company granted the following awards under the 2019 Plan:

Grant Date	Number of Shares	Type of Award	Exercise Price	Fair Value / Share
5/6/2021	210,000	Options	$ 4.92	$ 3.13
6/24/2021	313,000	Options	$ 5.90	$ 3.73
	523,000			

The allocation of employee stock-based compensation expense by functional area for the three and six months ended June 30, 2021 and 2020 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2021	2020	2021	2020
Cost of revenue	$ 48	$ 25	$ 78	$ 48
Research and development	93	1	118	1
Sales and marketing	325	43	465	80
General and administrative	316	293	488	494
Total	$ 782	$ 362	$ 1,149	$ 623

5. LOSS PER SHARE

The Company calculates basic loss per share using the weighted average number of shares of Aspira common stock outstanding during the period. Because the Company is in a net loss position, diluted loss per share is calculated using the weighted average number of shares of Aspira common stock outstanding and excludes the effects of 10,272,785 and 8,465,903 potential shares of Aspira common stock as of June 30, 2021 and 2020, respectively, that are anti-dilutive. Potential shares of Aspira common stock include incremental shares of Aspira common stock issuable upon the exercise of stock options and unvested restricted stock units.

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

Forward-Looking Statements

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

These statements involve a number of risks and uncertainties. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements speak only as of the date on which this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission (the "SEC"), and, except as required by law,

Aspira Women's Health Inc. ("Aspira" and, together with its subsidiaries, the "Company," "we," "our," or "us") does not assume any obligation to update, amend or clarify them to reflect events, new information or circumstances occurring after such date.

Examples of forward-looking statements include, without limitation:

- projections or expectations regarding our future test volumes, revenue, cost of revenue, operating expenses, research and development expenses, gross profit margin, cash flow, results of operations and financial condition;
- our plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders, including additional pelvic disease conditions such as endometriosis, in addition to genetics risk assessment, including breast and ovarian cancer hereditary risk assessment and carrier screening;
- our planned business strategy and strategic business drivers and the anticipated effects thereof;
- plans to commercialize OVA1, OVERA, OVA1plus, Aspira GenetiX, OVASight, EndoCheck, OVAInherit and Aspira Synergy on a global level;
- plans to develop new algorithms, molecular diagnostic tests, products and tools and otherwise expand our product offerings, including plans to develop a product using genetics, proteins and other modalities to assess the risk of developing cancer when carrying a pathogenic variant associated with hereditary breast and ovarian cancer that is difficult to detect through a diagnostic test;
- plans and timeline to establish payer coverage for OVERA, Aspira GenetiX, OVASight, EndoCheck and OVAInherit separately and expand coverage for OVA1;
- intentions to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and other issues in the fields of oncology and women's health;
- anticipated efficacy of our products, product development activities and product innovations, including our ability to improve sensitivity and specificity over traditional diagnostic biomarkers;
- expected competition in the markets in which we compete;
- plans with respect to ASPiRA LABS, including plans to expand ASPiRA LABS' testing capabilities;
- expectations regarding future services provided by Quest Diagnostics Incorporated;
- plans to develop informatics products and develop and perform laboratory developed tests ("LDTs");
- plans to develop a race and / or ethnicity-specific pelvic mass risk assessment;
- expectations regarding existing and future collaborations and partnerships for our products, including plans to enter into decentralized arrangements for our Aspira Synergy product;
- plans regarding future publications;
- our ability to continue to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests within the United States and internationally, as applicable;
- our continued ability to expand and protect our intellectual property portfolio;
- anticipated liquidity, capital requirements and future losses;
- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations;
- expectations regarding the results of our clinical utility 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, Aspira GenetiX and Aspira Synergy platform;
- expectations regarding our ability to launch new products we develop, or license, co-market or acquire new products;
- expectations regarding the size of the markets for our products;

expectations regarding reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans;
plans to use AbbVie Inc. serum samples in EndoCheck product validation studies;
expectations regarding the wind down of our ASPiRA IVD, Inc. subsidiary and future service revenue;
expectations in leveraging telehealth, including for the development of a process for patients to access Aspira GenetiX testing directly;
expected target launch date for OVASight;
compliance with federal and state laws and regulations relating to billing arrangements conducted in coordination with physician owned laboratories;
plans with respect to EndoCheck whether or not the FDA designates it a Breakthrough Device;
effectiveness of our efforts to advocate for legislation and professional society guidelines to broaden access to our products and services; and
expectations regarding the impacts resulting from or attributable to the COVID-19 pandemic and actions taken to contain it.

Forward-looking statements are subject to significant risks and uncertainties, including those discussed in Part I Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020, that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including impacts resulting from or relating to the COVID-19 pandemic and actions taken to contain it; anticipated use of capital and its effects; our ability to increase the volume of our product sales; failures by third-party payers to reimburse for our products and services or changes to reimbursement rates; our ability to continue developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform LDTs; our ability to comply with Food and Drug Administration ("FDA") regulations that relate to our products and to obtain any FDA clearance or approval required to develop and commercialize medical devices; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; or our suppliers' ability to comply with FDA requirements for production, marketing and post-market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; in the event that we succeed in commercializing our products outside the United States, the political, economic and other conditions affecting other countries; changes in healthcare policy; our ability to comply with environmental laws; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; our ability to use our net operating loss carryforwards; our ability to use intellectual property directed to diagnose biomarkers; 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 manufacturing operations.

Overview

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

Our plan is to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders. We plan to continue commercializing our new generation of technology and decentralized technology transfer service platform. We also intend to raise public awareness regarding the

diagnostic superiority of OVA1 as compared to cancer antigen 125 ("CA125") for Black women with adnexal masses. We also plan to advocate for legislation and professional society guidelines that provide broad access to our products and services.

We currently market and sell the following products and related services: (1) OVA1, a blood test designed to, in addition to a physician's clinical assessment of a woman with a pelvic mass, identify women who are at high-risk of having a malignant ovarian tumor prior to planned surgery; (2) OVERA, a second-generation biomarker panel intended to maintain OVA1's high sensitivity while improving specificity; (3) OVA1plus, a reflex offering which uses OVA1 and OVERA as a confirmation for OVA1 intermediate range results and leverages the strengths of OVA1's Multivariate Index Assay ("MIA") sensitivity and OVERA's (MIA2G) specificity and as a result reduces false elevations by over 40%; (4) Aspira GenetiX, a genetic test for gynecologic cancer risk, with a core focus on female reproductive cancers, including breast, ovarian, endometrial, uterine and cervical cancers; and (5) Aspira Synergy, our new decentralized platform and cloud service technology, which we plan to house our algorithms for decentralized global access. We plan to make OVA1, OVERA, OVA1plus and Aspira GenetiX available through Aspira Synergy. Our OVA1 algorithm received FDA de novo classification in September 2009, and our OVERA algorithm received FDA 501(k) clearance in March 2016. OVA1 and OVERA each use the Roche cobas 4000, 6000 and 8000 platforms for analysis of proteins. Through June 30, 2021, our product and related services revenue has been limited to revenue generated by sales of OVA1, OVA1plus and Aspira GenetiX. In 2021, we began to enter into decentralized arrangements with large healthcare networks and large practices for our Aspira Synergy product. In the second quarter of 2021, we secured our first decentralized arrangement using our Aspira Synergy platform with one of the largest women's care super groups in the U.S.

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

- OVASight is validated for use as a non-invasive risk assessment test used in conjunction with clinical assessment and imaging to determine ovarian cancer risk for patients with an adnexal mass for whom surgery is not currently recommended. A future revision of this test will be offered to women in this same cohort who have a low risk of ovarian cancer and who may benefit from serially monitoring their ovarian cancer risk over time. As such, OVASight will be applicable to a larger population than OVA1 based on its FDA cleared indication of use. OVASight will be launched during Q4 2021.
- EndoCheck, a blood test to be used in conjunction with other non-surgical modalities, will address the patient population of women who are experiencing moderate to severe pelvic pain and provide non-invasive surgical confirmation that their symptoms are indicative of endometriosis. The goal of this test is to support an early diagnosis and direct appropriate medical management that potentially reduces the progression of disease. Current detection methods for endometriosis require surgery and a surgical biopsy diagnosis and/or visualization diagnosis. EndoCheck is intended to address this large patient population using a non-invasive solution with both the sensitivity and specificity equal to or greater than surgical biopsy and/or visualization.
- OVAInherit will be designed as a high-risk diagnostic tool, intended for those patients with or without a pelvic mass who are genetically predisposed to gynecologic cancer. It will use genetics, proteins and other modalities to assess the risk of gynecologic cancers early without visible presence of cancer via traditional ultrasound methodologies. Our related trial, OVA360, has launched and will be focused on developing a diagnostic test for the early detection of ovarian cancer.

In addition, we continue to plan to accelerate the target launch date of OVASight to the fourth quarter of 2021. This test initially will allow physicians to assess benign pelvic masses with much better performing technology than CA125, and our next revision will allow a mass to be monitored over time. OVASight will leverage a high negative predictive value to rule out ovarian cancer risk, as well as high positive predictive value to rule in the risk of ovarian cancer.

We ultimately plan to commercialize each of OVA1, OVERA, OVA1plus, Aspira GenetiX, OVASight, EndoCheck and OVAInherit on a global level. We currently hold CE marks for OVA1 and OVERA. In addition, each of OVA1 and OVERA, and the reflex offering, OVA1plus, will be offered on our global testing platform, which allows both tests to be deployed worldwide.

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

We own and operate Aspira Labs, Inc. ("ASPiRA LABS"), based in Austin, Texas, a Clinical Chemistry and Endocrinology Laboratory accredited by the College of American Pathologists, which specializes in applying biomarker-based technologies to address critical needs in the management of gynecologic cancers and disease. ASPiRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based risk assessment to aid in clinical decision making and advance personalized treatment plans. The lab currently processes our OVA1 and OVERA tests, and we plan to expand the testing to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPiRA LABS. ASPiRA LABS holds a Clinical Laboratory Improvements Amendments of 1988 ("CLIA") Certificate of Accreditation and a state laboratory license in California, Maryland, New York, Pennsylvania and Rhode Island. This allows the lab test OVA1 and OVERA to be performed on a national basis. The Centers for Medicare & Medicaid Services ("CMS") issued a supplier number to ASPiRA LABS in 2015.

Recent Developments

Business, Product and Coverage Developments

Our proof-of-concept study with Dana Farber Cancer Institute/Harvard University is progressing and we expect to have preliminary data at the end of the third quarter of 2021. The goal is to combine our high sensitivity performance as reported with OVASight, with the high specificity by detecting miRNA in serum, to provide a multi-omics approach that can help eradicate late-stage ovarian cancer detection.

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

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

In June 2021, we presented an abstract at the American Society for Clinical Oncology conference, and we are currently working to publish both the analytical and clinical validation findings in the third quarter of 2021.

On May 12, 2021, the Company announced the execution an Aspira Synergy agreement with one of the largest women's health networks whereby the OVA1plus testing will be performed in its laboratory with data interpretation by Aspira. The health network employs 300+ physicians and is responsible for 500,000 patient visits per year.

On May 12, 2021, we announced the initiation of a large prospective study with The Feinstein Institutes for Medical Research, the science arm of Northwell Health, the largest private healthcare provider in New York State. Northwell Health treats over 2 million patients annually and employs over 16,000 credentialled physicians. The study will further support longitudinal studies for the use of OVASight as a serial monitoring test for high-risk women predisposed for hereditary ovarian cancer.

The FDA's Breakthrough Devices Program provides patients and health care providers with timely access to medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment and review. In the first quarter of 2021, we submitted to the FDA a Breakthrough Device designation request with respect to EndoCheck. We have been in communications with the FDA regarding our request and we plan to update the request based on the guidance we have received thus far regarding the need to show Endometriosis is an irreversible debilitating disease. The FDA has demonstrated interest in continuing to work with us on EndoCheck and we plan to continue our discussions with the agency on Breakthrough Device Program designation. There is no assurance that the FDA will grant our request for EndoCheck to be designated as a Breakthrough Device. If our device is granted a Breakthrough Device designation, we plan to move forward with interacting with the FDA through a variety of options including sprint discussions, a request for a discussion on a data development plan, and a request for clinical protocol agreement, and any final submission will be a de novo submission. If the FDA denies our request for a Breakthrough Device designation in the next six months, we plan to proceed with a LDT.

COVID-19 Pandemic

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. The novel coronavirus has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID-19, the disease caused by the novel coronavirus, a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the coronavirus outbreak. This outbreak has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. Patient enrollment for our planned research studies has been lower due to the impact of closures and restricted travel, which has led to delays in the completion of such studies. Our commercial efforts to enter into decentralized arrangements with large healthcare networks and supergroups have continued to move forward. However, finalization of such deals have been slowed by the pandemic. In addition, many conventions and industry conferences have been cancelled.

As a result of the COVID-19 pandemic and actions taken to contain it, the majority of our non-laboratory employees have been working remotely since March 2020, and we expect that they will continue to do so until the number of daily COVID-19 cases in the areas surrounding our offices consistently levels off or declines. In terms of business continuity, our lab operations require on site essential employees. As previously disclosed, we have put in place staffing and reagent contingency plans to ensure there is no down time at our lab. We believe the lab could continue to operate in the event any isolated infection were to impact a portion of the workforce. In addition, as of the date of the filing of this Form 10-Q, we have approximately four months of reagents, one of our key testing supplies, in stock, depending on volume of tests performed, and we are working with the manufacturer to ensure a consistent supply over the next six months.

We are committed to following recommended physical and social distancing guidelines in order to reduce the risk of infection for our employees. We have also decreased our travel and convention-related expenses. We have taken several measures to reduce the impact of the COVID-19 related closures and quarantines. For example, because our salespeople have experienced limitations on their ability to physically visit physician offices, we have implemented other means of coverage such as virtual sales representative meetings and increased digital sales and marketing. In March 2020, our sales team began making in-person calls to customers as determined on a state-by-state basis, in accordance with local guidelines. We have developed protocols and training for our team where physical visits are allowed to help ensure employee, customer and patient safety.

In the second quarter of 2021, our test volume increased 19% compared to the first quarter of 2021 as physician offices resumed a higher level of patient visits. 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.

On March 27, 2020, the U.S federal government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The CARES Act is an emergency economic stimulus package in response to the coronavirus outbreak which, among other things, provided loans, guarantees and subsidies to qualifying businesses and contained numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. We do not expect these tax provisions to have a material impact on our financial statements.

On April 10, 2020, we received a stimulus check of approximately $89,000 from the U.S. Department of Health and Human Services pursuant to the CARES Act.

On May 1, 2020, we were granted a loan (the "PPP Loan") from BBVA USA in the aggregate amount of $1,005,767, pursuant to the Paycheck Protection Program (the "PPP"), which was established under the CARES Act as administered by the U.S. Small Business Administration ("SBA"). In March 2021, we applied for forgiveness of the PPP Loan, and, effective May 27, 2021, the SBA confirmed the waiver of our repayment of the PPP Loan. The Company recognized a gain on forgiveness of debt of $1,005,767 and reduced long- and short-term indebtedness by the same amount. The Company remains subject to an audit of the PPP loan. See "Liquidity and Capital Resources" for more information.

Strategy

We are focused on execution of the following core strategic business drivers in women's pelvic mass assessment, starting with ovarian cancer diagnostics, and specialized laboratory services to build long-term value for our investors:

- Maximizing the existing OVA1plus opportunity in the United States by actively pursuing payer coverage and commercialization of OVA1plus;
- Expanding the distribution platform beyond the U.S. by launching OVA1plus (OVERA, a next generation biomarker panel, and OVA1 on the same platform), while building the clinical utility and health economics foundation of both OVA1 and OVERA, which we believe may allow for better domestic market penetration and international expansion;
- Finalizing clinical utility studies for OVA1 to further enhance payer coverage and reimbursement and launch clinical utility study for OVASight;
- Considering business development and M&A opportunities that represent synergistic offerings in women's health;
- Leveraging our existing database and specimen bank while building the largest specimen and data repository of gynecologic pelvic mass patients worldwide;
- Expanding our product offerings to additional women's health diseases with a focus on pelvic disease conditions such as pelvic mass monitoring and endometriosis by adding additional gynecologic bio-analytic solutions involving biomarkers, genetics, other modalities (e.g., imaging), clinical risk factors and patient data to aid diagnosis and risk stratification of women presenting with a pelvic mass;
- Coupling our OVA1 products with an individual's hereditary genetic risk to refine ovarian cancer risk assessment for high-risk populations;
- Establishing a proprietary decentralization platform, Aspira Synergy, to allow large healthcare networks and gynecologic practices to access OVA1 technology algorithms and genetics algorithms as a technology transfer service; and
- Working with governments, legislative bodies and advocacy groups to enhance awareness and drive policies that provide broader access to the Company's tests.

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

We have active international distribution agreements for OVERA with Pro-Genetics LTD in Israel and MacroHealth, Inc. in the Philippines. The MacroHealth, Inc. agreement was our first agreement regarding decentralized technology transfer for OVERA specimen testing.

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

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

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

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

In July 2021, we announced coverage for OVA1 in the AIM Specialty Health Laboratory Medicine Clinical Guidelines. Our OVA1 risk assessment test for ovarian cancer in women with pelvic masses is considered medically necessary according to AIM Specialty Health's Clinical Appropriateness Guidelines. AIM is a member of the Anthem Blue Cross Blue Shield family of companies, which promotes optimal care through use of evidence-based clinical guidelines and real-time decision support for both providers and their patients. AIM is a wholly owned subsidiary of Anthem, Inc., serving more than 50 million members across 50 states, D.C. and U.S. territories.

Recent Publications

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

The OVA1plus paper was accepted to the International Journal of Biological Markers, titled "A Two-Step Multivariate Index Assay Improves the Accuracy of Ovarian Cancer Risk Assessment for Women with an Adnexal Mass." It is expected to be published at a future date.

On August 10, 2021, a paper was published in a special edition of Diagnostics entitled *"Salvaging detection of early-stage ovarian malignancies when CA125 is not informative."* This paper further validates and supports the superior early-stage detection of ovarian cancer versus the current standard of care in a large population. The paper reports that in a retrospective study of 2,305 patients selected for low-risk or "normal" CA125 values, OVA1 detected over 50% of ovarian malignancies in premenopausal women which were not detected by CA125. In this study dataset, OVA1 also correctly identified 63% of early-stage cancers missed by CA125.

Critical Accounting Policies and Estimates

Our product revenue is generated by performing diagnostic services using our OVA1, OVERA, OVA1plus or ASPiRA GenetiX tests, and the service is completed upon the delivery of the test result to the

prescribing physician. The entire transaction price is allocated to the single performance obligation contained in a contract with a patient. Under ASC Topic 606*. Revenue from Contracts with Customers*, all revenue is recognized upon completion of the OVA1, OVERA, OVA1plus or ASPiRA GenetiX test and delivery of test results to the physician based on estimates of amounts that will ultimately be realized. In determining the amount of revenue to be recognized for a delivered test result, we consider factors such as payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and us, and any developments or changes that could impact reimbursement. These estimates require significant judgment by management. For OVA1, OVERA, OVA1plus and ASPiRA GenetiX tests, we also review our patient account population and determine an appropriate distribution of patient accounts by payer (*i.e.*, Medicare, patient pay, other third-party payer, *etc.*) into portfolios with similar collection experience. When evaluated for collectability, this results in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on an individual contract basis.

Results of Operations - Three Months Ended June 30, 2021 Compared to Three Months Ended June 30, 2020

The selected summary financial and operating data of the Company for the three months ended June 30, 2021 and 2020 were as follows:

	Three Months Ended June 30,		Increase (Decrease)	
(dollars in thousands)	**2021**	**2020**	**Amount**	**%**
Revenue:				
Product	$ 1,718	$ 726	$ 992	137
Genetics	79	17	62	365
Service	2	3	(1)	(33)
Total revenue	1,799	746	1,053	141
Cost of revenue:				
Product	825	458	367	80
Genetics	278	131	147	112
Service	-	4	(4)	-
Total cost of revenue	1,103	593	510	86
Gross profit	696	153	543	355
Operating expenses:				
Research and development	1,471	380	1,091	287
Sales and marketing	4,018	1,733	2,285	132
General and administrative	3,279	1,866	1,413	76
Total operating expenses	8,768	3,979	4,789	120
Loss from operations	(8,072)	(3,826)	(4,246)	111
Interest income, net	3	1	2	(200)
Other income (expense), net	995	(6)	1,001	16,683
Net loss	$ (7,074)	$ (3,831)	$ (3,243)	85

Product Revenue. Product revenue was $1,718,000 for the three months ended June 30, 2021 compared to $726,000 for the same period in 2020. Revenue for ASPiRA LABS is recognized when the OVA1, OVERA, or OVA1plus test is completed based on estimates of what we expect to ultimately realize. The 137% product revenue increase is primarily due to the lower number of tests performed in 2020 due to COVID-19, as well as an increase in OVA1 average revenue per test in 2021 compared to the prior year.

The number of OVA1plus tests performed increased 85% to 4,553 OVA1plus tests during the three months ended June 30, 2021 compared to 2,458 OVA1plus tests for the same period in 2020. Revenue increased due to increased access to offices, patients' return to physician visits, increased investment in our current commercial channel and new investment in our new healthcare system and Aspira Synergy commercial channels.

The revenue per OVA1plus test performed increased to approximately $377 compared to $295 for the same period in 2020, an increase of 28%. This increase was primarily driven by an increase in payments by contracted payers.

Genetics Revenue. Genetics revenue was $79,000 for the three months ended June 30, 2021, compared to $17,000 for the same period in 2020. Revenue for Aspira GenetiX is recognized when the Aspira GenetiX test is completed based on estimates of what we expect to ultimately realize. The 365% genetics revenue increase is primarily due to an increase in Aspira GenetiX test volume as we continued to market this product in 2021, as well as a higher revenue per test. The revenue per test performed increased to approximately $513 compared to $360, an increase of 42%, from the same period in 2020. This increase was primarily driven by an increase in payments by contracted payers. We expect revenue to continue to improve in the remainder of 2021, provided that the COVID-19 pandemic does not further escalate and result in new quarantines and state closures. The duration of the pandemic and efforts to contain it remains uncertain.

Service Revenue. Service revenue was $2,000 for the three months ended June 30, 2021 compared to $3,000 for the same period in 2020. Substantially all projects with ASPiRA IVD were finalized during 2019 and the subsidiary's operations were largely completed. Revenue for ASPiRA IVD was recognized once certain revenue recognition criteria had been met. We do not expect to have any significant service revenue in 2021 as the IVD trial services were largely wound down in 2019. However, the Company may continue to have some future legacy IVD activity in the second half of 2021.

Cost of Revenue – Product. Cost of product revenue was $825,000 for the three months ended June 30, 2021 compared to $458,000 for the same period in 2020, representing an increase of $367,000, or 80%, due primarily to increased test volume.

Cost of Revenue - Genetics. Cost of genetics revenue, which consisted primarily of personnel costs and consulting expense after the launch of Aspira GenetiX, was $278,000 for the three months ended June 30, 2021 compared to $131,000 for the same period in 2020. The increase in cost represented an increase of $64,000 in personnel costs, as well as an increase in volume as compared to the same period in 2020.

Gross Profit Margin. Gross profit margin for OVA1plus was 52.0% for the three months ended June 30, 2021 compared to 36.9% for the same period in 2020, an increase of 15.1%. Overall gross profit margin was 38.7% for the three months ended June 30, 2021 compared to 20.5% for the same period in 2020, an increase of 18.2%, due primarily to an increase in volume covering our fixed costs.

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 June 30, 2021 increased by $1,091,000, or 287%, compared to the same period in 2020. This increase was primarily due to clinical utility and product development costs related to OVASight, our third-generation product, as well as investments in bioinformatics, investments in Aspira Synergy and consulting expenses associated with EndoCheck regulatory clearance. We expect research and development expenses to increase in 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, and infrastructure expenses. These expenses include the costs of educating physicians and other healthcare professionals regarding OVA1, OVERA, OVA1plus and Aspira GenetiX. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the three months ended June 30, 2021 increased by $2,285,000, or 132%, compared to the same period in 2020. This increase was primarily due to increased personnel and consulting costs. We expect sales and marketing expenses to increase further in the second half of 2021, due to investing in key strategic hires and product portfolio expansion, as well as the continued re-openings relating to the COVID-19 pandemic, provided that the COVID-19 pandemic does not further escalate and result in new quarantines and state closures.

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 June 30, 2021 increased by $1,413,000, or 76%, compared to the same period in 2020. This increase was primarily due to an increase in headcount and personnel expenses, as well as stock compensation expenses. We expect general and administrative expenses to increase further in the second half of 2021 due to higher personnel costs.

Net Interest and Other Income (Expense). Net other income (expense) for the three months ended June 30, 2021 increased by $1,003,000, compared to the same period in 2020. Other income in the second quarter of 2021 consisted primarily of the forgiveness of the PPP Loan.

Results of Operations – Six Months Ended June 30, 2021 Compared to Six Months Ended June 30, 2020

The selected summary financial and operating data of the Company for the six months ended June 30, 2021 and 2020 were as follows:

	Six Months Ended June 30,		Increase (Decrease)	
(dollars in thousands)	**2021**	**2020**	**Amount**	**%**
Revenue:				
Product	$ 3,134	$ 1,911	$ 1,223	64
Genetics	159	42	117	279
Service	2	13	(11)	(85)
Total revenue	3,295	1,966	1,329	68
Cost of revenue:				
Product	1,473	1,123	350	31
Genetics	523	261	262	100
Service	-	9	(9)	-
Total cost of revenue	1,996	1,393	603	43
Gross profit	1,299	573	726	127
Operating expenses:				
Research and development	2,343	775	1,568	202
Sales and marketing	7,126	3,848	3,278	85
General and administrative	5,788	3,576	2,212	62
Total operating expenses	15,257	8,199	7,058	86
Loss from operations	(13,958)	(7,626)	(6,332)	83
Interest income, net	(21)	9	(30)	(333)
Other income (expense), net	985	80	905	1,131
Net loss	$ (12,994)	$ (7,537)	$ (5,457)	72

Product Revenue. Product revenue was $3,134,000 for the six months ended June 30, 2021 compared to $1,911,000 for the same period in 2020. Revenue for ASPiRA LABS is recognized when the OVA1, OVERA, or OVA1plus test is completed based on estimates of what we expect to ultimately realize. The 64% product revenue increase is primarily due to the lower number of tests performed in 2020 due to COVID-19 closures, as well as an increase in OVA1 average revenue per test in 2021 compared to the prior year.

The number of OVA1plus tests performed increased 36% to 8,328 OVA1plus tests during the six months ended June 30, 2021 compared to 6,112 OVA1plus tests for the same period in 2020. Revenue increased due to increased access to offices, patients' return to physician visits, increased investment in our current commercial channel and new investment in our new healthcare system and Aspira Synergy commercial channels.

The revenue per OVA1plus test performed increased to approximately $376 compared to $313 for the same period in 2020, an increase of 20%. This increase was primarily driven by an increase in payments by contracted payers.

Genetics Revenue. Genetics revenue was $159,000 for the six months ended June 30, 2021, compared to $42,000 for the same period in 2020. Revenue for Aspira GenetiX is recognized when the Aspira GenetiX test is completed based on estimates of what we expect to ultimately realize. The 279% genetics revenue increase is primarily due to an increase in Aspira GenetiX test volume as we continued to market this product in 2021, as well as a higher revenue per test. The revenue per test performed increased to approximately $483 compared to $270, and increase of 79%, for the same period in 2020. This increase was primarily driven by an increase in payments by contracted payers. We expect revenue to continue to improve in the second half of 2021, provided that the COVID-19 pandemic does not further escalate and result in new quarantines and state closures. The duration of the pandemic and efforts to contain it remains uncertain.

Service Revenue. Service revenue was $2,000 for the six months ended June 30, 2021 compared to $13,000 for the same period in 2020. Substantially all projects with ASPiRA IVD were finalized during 2019 and the subsidiary's operations were largely completed. Revenue for ASPiRA IVD was recognized once certain revenue recognition criteria had been met. We do not expect to have any significant service revenue in 2021 as the IVD trial services were largely wound down in 2019. However, the Company may continue to have some future legacy IVD activity in 2021.

Cost of Revenue – Product. Cost of product revenue was $1,473,000 for the six months ended June 30, 2021 compared to $1,123,000 for the same period in 2020, representing an increase of $350,000, or 31%, due primarily to increased test volume.

Cost of Revenue - Genetics. Cost of genetics revenue, which consisted primarily of personnel costs and consulting expense after the launch of Aspira GenetiX, was $523,000 for the six months ended June 30, 2021 compared to $261,000 for the same period in 2020. The increase in cost represented $129,000 increase in personnel costs, as well as an increase in volume as compared to the same period in 2020.

Gross Profit Margin. Gross profit margin for OVA1plus was 53.0% for the six months ended June 30, 2021 compared to 41.2% for the same period in 2020, an increase of 11.8%. Overall gross profit margin was 39.4% for the six months ended June 30, 2021 compared to 29.1% for the same period in 2020, an increase of 10.3%, due primarily to an increase in volume covering our fixed costs.

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 six months ended June 30, 2021 increased by $1,568,000, or 202%, compared to the same period in 2020. This increase was primarily due to clinical utility and product development costs related to OVASight, our third-generation product, as well as investments in bioinformatics, investments in Aspira Synergy and consulting expenses associated with EndoCheck regulatory clearance. We expect research and development expenses to increase in 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, and infrastructure expenses. These expenses include the costs of educating physicians and other healthcare professionals regarding OVA1, OVERA, OVA1plus and Aspira GenetiX. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the six months ended June 30, 2021 increased by $3,278,000, or 85%, compared to the same period in 2020. This increase was primarily due to increased personnel related costs. We expect sales and marketing expenses to increase further in the second half of 2021, due to investing in key strategic hires and product portfolio expansion, as well as the continued re-openings relating to the COVID-19 pandemic, provided that the COVID-19 pandemic does not further escalate and result in new quarantines and state closures.

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 six months ended June 30, 2021 increased by $2,212,000, or 62%, compared to the same period in 2020. This increase was primarily due to an increase in headcount and personnel expenses, as well as stock compensation expenses. We expect general and administrative expenses to increase further in the second half of 2021 due to higher personnel costs.

Net Interest and Other Income (Expense). Net interest income and other income (expense) for the six months ended June 30, 2021 increased by $875,000 compared to the same period in 2020. Other income in the second quarter of 2021 consisted primarily of forgiveness of the PPP Loan.

Liquidity and Capital Resources

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

On February 8, 2021, the Company completed a public offering (the "2021 Offering"), resulting in net proceeds to the Company of approximately $47.7 million, after deducting underwriting discounts and offering expenses.

On July 20, 2020, the Company completed a private placement pursuant to which certain investors purchased 3,150,000 shares of Aspira common stock at a per share price of $3.50. Net proceeds of the private placement were approximately $10.6 million, after deducting underwriting discounts and offering expenses.

In early June 2020, we issued 2,810,338 shares of Aspira common stock upon the exercise of all of our outstanding warrants and received approximately $5.1 million in aggregate proceeds therefrom.

On May 1, 2020, the Company obtained the PPP Loan from BBVA USA in the aggregate amount of $1,005,767. The application for these funds required the Company to, in good faith, certify that the described economic uncertainty at the time made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to consider its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that was not significantly detrimental to the business. Under the terms of the CARES Act and the PPP Loan, all or a portion of the principal amount of the PPP Loan was subject to forgiveness so long as, over the 24-week period following the Company's receipt of the proceeds of the PPP Loan, the Company used those proceeds for payroll costs, rent, utility costs or the maintenance of employee and compensation levels. The PPP Loan, which was granted pursuant to a promissory note, was set to mature on May 1, 2022. The Company applied for forgiveness of the PPP Loan in March 2021, and, effective May 27, 2021, the SBA confirmed the waiver of the Company's repayment of the PPP Loan. The Company recognized a gain on forgiveness of debt of $1,005,767 and reduced long- and short-term indebtedness by the same amount. The Company remains subject to an audit of the PPP loan. There is no assurance that the Company will not be required to repay all or a portion of the PPP Loan as a result of the audit.

On March 22, 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 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, we have granted the DECD a blanket security interest in our personal and intellectual property. The DECD's security interest in our 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 us 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 we 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 does not maintain our Connecticut operations through March 22, 2026, the DECD may require early repayment of a portion or all of the loan plus a penalty of 5% of the total funded loan. For additional information, see Note 3 of our consolidated financial statements.

The Company has incurred significant net losses and negative cash flows from operations since inception. At June 30, 2021 we had an accumulated deficit of $453,060,000 and stockholders' equity of $55,829,000. As of June 30, 2021, we had $52,993,000 of cash and cash equivalents and $5,791,000 of current liabilities. Working capital was $49,116,000 and $12,603,000 at June 30, 2021 and December 31, 2020, respectively. There can be no assurance that we will achieve or sustain profitability or positive cash flow from operations. In addition, while we expect to grow revenue through ASPiRA LABS, there is no assurance of our ability to generate substantial revenues and cash flows from ASPiRA LABS' operations. We expect revenue from our products and services to be our only material, recurring source of cash in 2021.

Net cash used in operating activities was $11,745,000 for the six months ended June 30, 2021, resulting primarily from the net loss reported of $12,994,000, which includes non-cash items such as stock compensation expense of $1,771,000, PPP loan forgiveness of $1,005,767 and depreciation and amortization of $172,000, offset by changes in prepaid expense and other assets of $350,000 and changes in accounts payable, accrued and other liabilities of $208,000, partially offset by, changes in accounts receivable of $208,000, and inventory of $71,000.

Net cash used in operating activities was $6,911,000 for the six months ended June 30, 2020, resulting primarily from the net loss reported of $7,537,000, changes in prepaid expenses of $99,000 and changes in accounts payable, accrued and other liabilities of $165,000, partially offset by stock compensation expense of $710,000, changes in depreciation and amortization of $114,000 and changes in accounts receivable of $105,000.

Net cash used in investing activities was $136,000 and $123,000 for the six months ended June 30, 2021 and 2020, respectively, which consisted of property and equipment purchases.

Net cash provided by financing activities was $48.2 million for the six months ended June 30, 2021, which resulted primarily from the February 2021 public offering, resulting in net proceeds to the Company of approximately $47.7 million, after deducting underwriting discounts and offering expenses.

Net cash provided by financing activities was $6.3 million for the six months ended June 30, 2020, which resulted primarily from the exercise of the warrants from the 2020 exercise of warrants of approximately $5.1 million and the PPP Loan of $1.0 million in 2020.

We expect to incur a net loss and negative cash flows from operations in 2021. The impact of the COVID-19 pandemic and actions taken to contain it on our liquidity for 2021 cannot be estimated as of the date of this filing.

However, we believe that our cash and cash equivalents will be sufficient to fund our operations for the next twelve months.

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

- resources devoted to sales, marketing and distribution capabilities;
- the rate of OVA1, OVERA, OVA1plus and Aspira GenetiX product adoption by physicians and patients;
- the rate of product adoption by healthcare systems and large physician practices of the decentralized distribution agreements for OVA1, OVERA and OVA1plus;

the insurance payer community's acceptance of and reimbursement for our products;

our plans to acquire or invest in other products, technologies and businesses;
the market price of our common stock;
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.

We have significant net operating loss ("NOL") carryforwards as of June 30, 2021 for which a full valuation allowance has been provided due to our history of operating losses. Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state provisions may restrict our ability to use our NOL credit carryforwards due to ownership change limitations occurring in the past or that could occur in the future. These ownership changes may also limit the amount of NOL credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

Legislation commonly referred to as the Tax Cuts and Jobs Act (H.R. 1) was enacted on December 22, 2017. As a result of the Tax Cuts and Jobs Act of 2017, federal NOLs arising before January 1, 2018, and federal NOLs arising after January 1, 2018, are subject to different rules. The Company's pre- 2018 federal NOLs will expire in varying amounts from 2021 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 2021 through 2037 if not utilized. The Company's ability to use its NOLs during this period will be dependent on the Company's ability to generate taxable income, and the NOLs could expire before the Company generates sufficient taxable income.

The Company believes that Section 382 ownership changes occurred as a result of the Company's follow-on public offerings in 2011, 2013, and 2015. Any limitation may result in the expiration of a portion of the net operating loss and tax credit carryforwards before utilization and any net operating loss and tax credit carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the Company's valuation allowance. Due to the existence of a valuation allowance, it is not expected that such limitations, if any, will have an impact on the Company's results of operations or financial position. The Company is still assessing whether the 2021 Offering resulted in a Section 382 ownership change.

Off-Balance Sheet Arrangements

As of June 30, 2021, 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 June 30, 2021. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2021, 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 June 30, 2021, 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 2020 Annual Report, filed with the SEC on March 31, 2021. The risks and uncertainties described below and in our 2020 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.

Failures by third-party payers to reimburse for our products and services or changes in reimbursement rates could materially and adversely affect our business, financial condition and results of operations. In addition, changes in medical society guidelines may also adversely affect payers and result in a change in coverage materially, adversely affecting our business, financial condition and results of operations.

We are responsible for obtaining payment from third-party payers. Accordingly, our future revenues will be dependent upon third-party reimbursement payments to ASPiRA LABS. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to change and particularly volatile during the early stages of commercialization. There remain questions as to what extent third-party payers, like Medicare, Medicaid and private insurance companies will provide coverage for OVA1, OVERA, OVA1plus, Aspira GenetiX and Aspira Synergy and for which indications. While CMS has issued Protecting Access to Medicare Act of 2014 ("PAMA") reimbursement rates for OVA1 and OVERA effective January 1, 2018, there is no guarantee that CMS will continue to cover the OVA1 test or that the payment rate will be comparable to the PAMA rate. Although the PAMA legislation allows for no more than a 15% fee reduction between 2021 and 2023, uncertainty regarding reimbursement rates could create payment uncertainty from other payers as well. The reimbursement rates for OVA1, OVERA, OVA1plus, OVASight, Aspira GenetiX and Aspira Synergy are largely out of our control. We have experienced volatility in the coverage and reimbursement of OVA1 and OVERA due to contract negotiation with third-party payers and implementation requirements, and the reimbursement amounts we have received from third-party payers varies from payer to payer, and, in some cases, the variation is material.

Third-party payers, including private insurance companies as well as government payers such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization of diagnostic tests such as OVA1 and OVERA. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in third-party payer reimbursement rates may occur in the future. Reductions in the price at which OVA1 and OVERA is reimbursed could have a material adverse effect on our business, results of operations and financial condition. If we are unable to establish and maintain broad coverage and reimbursement for our products or if third-party payers change their coverage or reimbursement policies with respect to our products, our business, financial condition and results of operations could be materially adversely affected.

The novel coronavirus outbreak and the COVID-19 pandemic have adversely impacted, and are expected to further adversely impact, our business, results of operations and financial condition, and such future adverse impact may be material. In addition, other health epidemics, outbreaks or pandemics may adversely affect our business, results of operations and financial condition.

We face risks related to health epidemics and other outbreaks, including the global outbreak of the novel coronavirus and the disease caused by it, COVID-19. Beginning in March 2020, the COVID-19 pandemic and actions taken to contain it have led to travel restrictions, stay-at-home mandates and limitations on access to hospitals and other medical facilities. As a result, our test volumes decreased for a period of time but have recovered, as fewer new patients were tested particularly from March to August 2020 and existing patients extended planned testing schedules. In addition, travel restrictions and stay-at-home mandates have limited recruitment of individuals to participate in our research studies, which has caused delays in our product development timelines. Our salespeople have been limited in their ability to make in-person sales calls. Although we have adjusted our commercialization efforts to incorporate virtual sales meetings and increased digital sales and marketing, those efforts may be less effective than in-person meetings to promote use of our products.

Although the spread of COVID-19 and actions taken to contain it lessened in the first quarter of 2021, if infection rates rise or if significant action is taken to contain the pandemic, we will likely experience test volume decreases and challenges for our sales force and efforts to recruit participants in studies, and our business, results of operations and financial condition are likely to be adversely affected. To the extent our testing volumes decrease or we are unable to collect from patient payers, our revenues, cash flows from operations and liquidity will be adversely impacted. There is no assurance that sales or collections will return to normal levels during 2021 or at any time thereafter.

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 May 6, 2021	8-K	001-34810	3.2	May 10, 2021	
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

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: August 12, 2021

/s/ Valerie B. Palmieri
Valerie B. Palmieri
President and Chief Executive Officer
(Duly Authorized Officer and
Principal Executive Officer)

Date: August 12, 2021

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