UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2019

OR

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

Commission file number: 001-34810

Vermillion, 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)

(512) 519-0400

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

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	VRML	The Nasdaq Stock Exchange

As of April 30, 2019, the registrant had 75,580,474 shares of common stock, par value $0.001 per share, outstanding.

VERMILLION, INC.

FORM 10-Q
For the Quarter Ended March 31, 2019
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ITEM 1. FINANCIAL STATEMENTS

Vermillion, Inc.
Condensed Consolidated Balance Sheets
(Amounts in Thousands, Except Share and Par Value Amounts)
(Unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 6,174	$ 9,360
Accounts receivable	699	786
Prepaid expenses and other current assets	605	550
Inventories	98	92
Total current assets	7,576	10,788
Property and equipment, net	531	608
Other assets	147	12
Total assets	$ 8,254	$ 11,408
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,157	$ 950
Accrued liabilities	1,879	1,825
Short-term debt	190	189
Other current liabilities	110	-
Total current liabilities	3,336	2,964
Non-current liabilities:		
Long-term debt	1,244	1,292
Other non-current liabilities	37	-
Total liabilities	4,617	4,256
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2019 and December 31, 2018	-	-
Common stock, par value $0.001 per share, 150,000,000 shares authorized at March 31, 2019 and December 31, 2018; 75,532,748 and 75,501,394 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	75	75
Additional paid-in capital	414,202	414,001
Accumulated deficit	(410,640)	(406,924)
Total stockholders' equity	3,637	7,152
Total liabilities and stockholders' equity	$ 8,254	$ 11,408

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.
Condensed Consolidated Statements of Operations
(Amounts in Thousands, Except Share and Per Share Amounts)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Revenue:		
Product	$ 779	$ 613
Service	24	36
Total revenue	803	649
Cost of revenue[1]:		
Product	516	533
Service	178	270
Total cost of revenue	694	803
Gross profit (loss)	109	(154)
Operating expenses:		
Research and development[2]	209	142
Sales and marketing[3]	2,364	1,225
General and administrative[4]	1,255	1,314
Total operating expenses	3,828	2,681
Loss from operations	(3,719)	(2,835)
Interest income (expense), net	7	(12)
Other income (expense), net	(4)	(3)
Net loss	$ (3,716)	$ (2,850)
Net loss per share - basic and diluted	$ (0.05)	$ (0.05)
Weighted average common shares used to compute basic and diluted net loss per common share	75,507,532	60,037,161
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:		
(1) Cost of revenue	$ 16	$ 30
(2) Research and development	2	1
(3) Sales and marketing	22	43
(4) General and administrative	144	108

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(Amounts in Thousands, Except Share Amounts)
(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	-	$ -	75,501,394	$ 75	$ 414,001	$ (406,924)	$ 7,152
Net loss	-	-	-	-	-	(3,716)	(3,716)
Common stock issued in conjunction with exercise of stock options	-	-	19,687	-	17	-	17
Common stock issued for restricted stock awards	-	-	11,667	-	3	-	3
Stock compensation charge	-	-	-	-	181	-	181
Balance at March 31, 2019	-	$ -	75,532,748	$ 75	$ 414,202	$ (410,640)	$ 3,637

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	-	$ -	60,036,017	$ 60	$ 399,400	$ (396,053)	$ 3,407
Net loss	-	-	-	-	-	(2,850)	(2,850)
ASC 606 adjustment to retained earnings	-	-	-	-	-	500	500
Common stock issued for restricted stock awards	-	-	3,321	-	6	-	6
Stock compensation charge	-	-	-	-	176	-	176
Balance at March 31, 2018	-	$ -	60,039,338	$ 60	$ 399,582	$ (398,403)	$ 1,239

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.
Condensed Consolidated Statements of Cash Flows
(Amounts in Thousands)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (3,716)	$ (2,850)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	124	186
Stock-based compensation expense	184	182
Loss on sale and disposal of property and equipment	1	-
Changes in operating assets and liabilities:		
Accounts receivable	87	(58)
Prepaid expenses and other assets	(43)	10
Inventories	(6)	-
Accounts payable, accrued liabilities and other liabilities	261	173
Net cash used in operating activities	(3,108)	(2,357)
Cash flows from investing activities:		
Purchase of property and equipment	(49)	(24)
Proceeds from sale of property and equipment	1	-
Net cash used in investing activities	(48)	(24)
Cash flows from financing activities:		
Proceeds from private placement offering of common stock, net of issuance costs	-	-
Principal repayment of DECD loan	(47)	(46)
Repayment of capital lease obligations	-	(9)
Proceeds from issuance of common stock from exercise of stock options	17	-
Net cash used in financing activities	(30)	(55)
Net decrease in cash and cash equivalents	(3,186)	(2,436)
Cash and cash equivalents, beginning of period	9,360	5,539
Cash and cash equivalents, end of period	$ 6,174	$ 3,103
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	11	12
Supplemental disclosure of noncash investing and financing activities:		
Net increase in other assets/other liabilities for right of use assets	147	-

See accompanying notes to the unaudited condensed consolidated financial statements.

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

Organization

Vermillion, Inc. ("Vermillion"; Vermillion and its wholly-owned subsidiaries are collectively referred to as the "Company," "we" or "our") is incorporated in the state of Delaware, and is engaged in the business of developing and commercializing diagnostic tests for gynecologic disease. The Company sells OVA1™ and Overa™ risk of malignancy tests for ovarian cancer ("OVA1" and "Overa," respectively) through Vermillion's wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, Inc. ("ASPiRA LABS").

The Company also offers in-vitro diagnostic ("IVD") trial services to third-party customers through its wholly-owned subsidiary, ASPiRA IVD, Inc. ("ASPiRA IVD"), which commenced operations in June 2016. ASPiRA IVD is a specialized, CLIA certified, laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays.

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 $410,640,000 at March 31, 2019. The Company also expects to incur a net loss and negative cash flows from operations for 2019. There can be no assurance that the Company will achieve or sustain profitability or positive cash flow from operations. Management expects cash from product and ASPiRA IVD sales to be the Company's only material, recurring source of cash in 2019. Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

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

As discussed in Note 4, on April 17, 2018, the Company completed two public offerings (the "Offerings"), pursuant to which certain investors purchased Vermillion common stock and Vermillion Series B convertible preferred stock for net proceeds of approximately $13,500,000 after deducting offering expenses.

As discussed in Note 4, on August 31, 2017, certain investors exercised outstanding warrants to purchase shares of Vermillion common stock for net proceeds of approximately $3,577,000 after deducting offering expenses.

As discussed in Note 4, on February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased Vermillion common stock and warrants to purchase shares of Vermillion common stock for net proceeds of approximately $5,127,000 after deducting offering expenses.

As discussed in Note 3, in March 2016, the Company entered into an agreement (the "Loan Agreement") pursuant to which it may borrow up to $4,000,000 from the State of Connecticut Department of Economic and Community Development (the "DECD"). An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The remaining $2,000,000 will be advanced if and when the Company achieves certain future milestones. The loan may be prepaid at any time without premium or penalty.

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, 2018 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, 2018 included in Vermillion's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 28, 2019 (the "2018 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.

Significant Accounting and Reporting Policies

Revenue Recognition

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), which it adopted on January 1, 2018 using the modified retrospective method. In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods and services.

Product Revenue

The Company's product revenue is generated by performing diagnostic services using its OVA1 and Overa 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. All revenue is recognized upon completion of the OVA1 or Overa test 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 current 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 reviewed its patient account population and determined 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. There were no impairment losses on accounts receivable recorded during the three months ended March 31, 2019.

Service Revenue

The Company's service revenue is generated by performing IVD trial services for third-party customers. Measurement of progress on contracts with customers will generally be based on the input measurement of cost incurred relative to the total expected costs to satisfy the performance obligation.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), Compensation - Stock Compensation ("ASU 2016-09"). The new guidance simplifies several aspects of the accounting for share-based payments, including immediate recognition of all excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within that reporting period. The Company adopted this standard on January 1, 2018, and the adoption did not have a material impact on the consolidated financial statements. In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Base Payment Accounting. This new guidance expands the scope of Topic 718 to include share-based payment transactions from acquiring goods and services from nonemployees, which was previously codified under Topic 505, where this change will modify the measurement requirements of nonemployee awards. This amendment is effective for annual periods after December 15, 2018. The Company adopted this standard on January 1, 2019 and its impact was not material.

In February 2016, the FASB issued ASU No. 2016-2, Leases (Topic 842*)* ("ASU 2016-2"). This guidance is intended to make leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-2 will be effective for interim and annual periods beginning after December 15, 2018. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited and early adoption is permitted. The Company adopted ASU 2016-02 effective January 1, 2019 and elected the package of practical expedients and the new transition approach permitted by ASU 2018-11. ASU 2018-11 allows the Company not to reassess existing identification of leases, classification of leases or any initial direct costs. The Company has also elected to use the hindsight practical expedient. The Company has two office leases which are required to be recorded as Right of Use ("ROU") assets and corresponding lease liabilities on the balance sheet. The Company has no short term leases with terms of less than twelve months. The Company recognized ROU assets and a lease liability of approximately $178,000 related to its leases on its consolidated balance sheet as of January 1, 2019. The Company did not have a cumulative adjustment impacting retained earnings.

In May 2014, the FASB issued ASC 606, which superseded existing revenue recognition guidance. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 effective on January 1, 2018 using the modified retrospective method. Please see the above "Revenue Recognition" section for a discussion of the Company's revenue recognition under ASC 606.

2. AGREEMENTS WITH QUEST DIAGNOSTICS INCORPORATED

In March 2015, the Company entered into a commercial agreement with Quest Diagnostics, Incorporated ("Quest Diagnostics"). Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Vermillion's wholly-owned subsidiary, ASPiRA LABS, as of August 2015. Pursuant to this agreement, as amended as of March 1, 2018, Quest Diagnostics is continuing to provide blood draw and logistics

support by transporting specimens from its clients to ASPiRA LABS for testing through at least March 11, 2019 in exchange for a market value fee. Per the terms of the commercial agreement, the Company will not offer to existing or future Quest Diagnostics customers tests that Quest Diagnostics offers. As of the date of this Quarterly Report on Form 10-Q, we are in the process of renewing this agreement.

3. COMMITMENTS AND CONTINGENCIES

Development Loan

On March 22, 2016, the Company entered into the Loan Agreement with the DECD, pursuant to which the Company may borrow up to $4,000,000 from the DECD. Proceeds from the loan were utilized primarily to fund the build-out, information technology infrastructure and other costs related to the Company's Trumbull, Connecticut facility and operations. 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. Under the terms of the Loan Agreement, as amended, the Company may be eligible for forgiveness of up to $2,000,000 of the principal amount of the loan if the Company achieves certain job creation and retention milestones by March 1, 2021 (the "Measurement Date"). Conversely, if the Company is either unable to meet these job creation and retention milestones, namely, hiring and retaining for a consecutive two-year period 40 full-time employees with a specified average annual salary by the Measurement Date, or does not maintain the Company's Connecticut operations for a period of 10 years, the DECD may require early repayment of a portion or all of the loan depending on job attainment as compared to the required amount plus a penalty of 5% of the total funded loan.

An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The remaining $2,000,000 will be advanced if and when the Company achieves certain other future milestones. The loan may be prepaid at any time without premium or penalty.

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 by ASPiRA IVD is located in Trumbull, Connecticut. The Austin, Texas lease expires on January 31, 2020 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. The term of the lease is five years beginning after the initial date of occupancy in January 2016 and a rent abatement period of five months, with two subsequent five-year renewal options at a rate equal to 90% of the then current fair market rate.

As of the date of the implementation of the new lease standard, ASU 2016-2, the Company is not reasonably certain to exercise the renewal option for its Trumbull, Connecticut lease due to the uncertain nature of its pricing.

The expense associated with these operating leases is shown in the table below (in thousands).

Lease Cost	Classification	Three Months Ended March 31 2019	2018
Operating rent expense			
	Cost of revenue	$ 9	$ 25
	Research and development	4	7
	Sales and marketing	8	12
	General and administrative	11	22
Variable rent expense			
	Cost of revenue	$ 12	$ 0
	Research and development	3	0
	Sales and marketing	10	0
	General and administrative	14	1

Based on our leases as of March 31, 2019, the table below sets forth the approximate future lease payments related to operating leases with initial terms of one year or more (in thousands).

2019	$ 128
2020	40
2021	14
Total Operating Lease Payments	182
Less: Interest	(4)
Present Value of Lease Liabilities	178

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

Weighted-average remaining lease term (in years)	1.5
Weighted-average discount rate	2.50%

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. Under the terms of the amended research collaboration agreement, Vermillion is required to pay the greater of 4% royalties on net sales of diagnostic tests using the assigned patents or annual minimum royalties of $57,500. Royalty expense for the three months ended March 31, 2019 and 2018 totalled $31,000 and $24,000, respectively.

4. STOCKHOLDERS' EQUITY

2018 Offerings

On April 13, 2018, the Company entered into two underwriting agreements (each, an "Underwriting Agreement") with Piper Jaffray & Co., as the sole underwriter (the "Underwriter"), in connection with separate but concurrent public offerings of the Company's securities.

Pursuant to the first Underwriting Agreement, the Company agreed to issue and sell an aggregate of 10,000,000 shares of Vermillion common stock, par value $0.001 per share, offered by the Underwriter in a public offering at a price to the public of $1.00 per share (the "Common Stock Offering"). Under this Underwriting

Agreement, the Company granted the Underwriter an option to purchase up to an additional 1,500,000 shares of Vermillion common stock at the public offering price, less underwriting discounts and commissions, to cover over-allotments, if any. The Underwriter did not exercise this option. The Common Stock Offering closed on April 17, 2018 and resulted in proceeds, net of 7% underwriting costs and other offering costs, to the Company of $8,992,000.

Pursuant to the second Underwriting Agreement, the Company agreed to issue and sell an aggregate of 50,000 shares of Vermillion Series B Convertible Preferred Stock, par value $0.001 per share, offered by the Underwriter in a public offering at a price to the public of $100.00 per share (the "Series B Offering"). The Series B Offering closed on April 17, 2018 and resulted in proceeds, net of 7% underwriting costs and other offering costs, to the Company of $4,496,000.

Upon obtaining Company stockholder approval at the annual meeting of Company stockholders on June 21, 2018, each of the 50,000 shares of Vermillion Series B Convertible Preferred Stock was automatically converted into shares of Vermillion common stock, at a conversion rate of 100 shares of Vermillion common stock per one share of Vermillion Series B Convertible Preferred Stock, including shares issuable pursuant to customary anti-dilution provisions.

2017 Warrant Repricing and Exercise

In December 2014, the Company issued warrants to purchase up to an aggregate of 4,166,659 shares of Vermillion common stock at an exercise price of $2.00 per share in conjunction with a December 2014 private placement of Vermillion common stock.

On August 31, 2017, certain holders of these warrants exercised warrants to purchase 3,796,818 shares of Vermillion common stock in consideration for the Company agreeing to reduce the exercise price to $1.00 per share of Vermillion common stock. The remaining 369,841 unexercised warrants expired by their original terms on December 23, 2017.

The Company issued 3,796,818 shares of Vermillion common stock and received $3,796,818 in aggregate gross proceeds (approximately $3,577,000 net of transaction costs). The incremental non-cash fair value of approximately $942,000 from the modification of the warrants was calculated using the Black-Scholes model and recorded as a deemed dividend to the warrant holders within stockholders' equity.

2017 Private Placement

On February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased 3,747,125 shares of Vermillion common stock at a price of $1.40 per share. Vermillion also issued warrants to purchase shares of Vermillion common stock at a price of $0.125 per warrant share in the private placement. Net proceeds of the private placement were approximately $5,127,000 after deducting offering expenses. The warrants are exercisable for 2,810,338 shares of Vermillion common stock at $1.80 per share. The warrants expire on the fifth anniversary of the date of issuance or, if earlier, five business days after Vermillion delivers notice that the closing price per share of its common stock exceeded the exercise price for 20 consecutive trading days during the exercise period.

The sale of common stock and issuance of warrants qualified for equity treatment under GAAP. The respective values of the warrants and common stock were calculated using their relative fair values and classified under common stock and additional paid-in capital. The value ascribed to the warrants is $804,000 and to the common stock is approximately $4,323,000.

2010 Stock Incentive Plan

The Company's employees, directors, and consultants are eligible to receive awards under the Vermillion, Inc. Second Amended and Restated 2010 Stock Incentive Plan (the "2010 Plan"). The 2010 Plan permits the granting of a variety of awards, including stock options, share appreciation rights, restricted shares, restricted share units, unrestricted shares, deferred share units, performance and cash-settled awards, and dividend equivalent rights.

The 2010 Plan provides for issuance of up to 12,122,983 shares of Vermillion common stock, subject to adjustment as provided in the 2010 Plan.

Stock-Based Compensation

During the three months ended March 31, 2019, the Company awarded Vermillion's non-employee directors an aggregate of 190,909 shares of restricted stock under the 2010 Plan having a fair value of approximately $252,000. The vesting of these shares of restricted stock is as follows: 25% on April 1, 2019, 25% on June 1, 2019, 25% on September 1, 2019 and 25% on December 1, 2019. During the three months ended March 31, 2019, the Company also granted Vermillion's non-employee directors options to purchase an aggregate of 402,584 shares of Vermillion common stock with an exercise price of $1.29 per share.

During the three months ended March 31, 2019, the Company awarded certain consultants 11,667 shares of restricted stock under the 2010 Plan having a fair value of approximately $10,000. During the three months ended March 31, 2019, the Company also granted certain consultants options to purchase 50,000 shares of Vermillion common stock with an exercise price of $0.47 per share. These stock options have performance-based vesting based on certain metrics through March 31, 2020. The Company also granted certain consultants options to purchase an aggregate of 100,000 shares of Vermillion common stock with an exercise price of $1.29 per share.

During the three months ended March 31, 2019, the Company granted certain officers and employees options to purchase an aggregate of 575,000 shares of Vermillion common stock with an exercise price of $0.47 per share. These stock options have performance-based vesting based on certain metrics through March 31, 2020. The Company also granted certain officers and employees options to purchase an aggregate of 55,000 shares of Vermillion common stock with an exercise price of $0.71 per share, 125,000 shares of Vermillion common stock with an exercise price of $0.77 and 1,073,000 shares of Vermillion common stock with an exercise price of $1.29 per share. These stock options vest 25% on each of the four anniversaries of the vesting commencement date for each such stock option.

The allocation of employee stock-based compensation expense by functional area for the three months ended March 31, 2019 and 2018 was as follows:

	Three Months Ended March 31,	
(in thousands)	**2019**	**2018**
Cost of revenue	$ 12	$ 24
Research and development	2	1
Sales and marketing	20	47
General and administrative	143	139
Total	$ 177	$ 211

5. LOSS PER SHARE

The Company calculates basic loss per share using the weighted average number of shares of Vermillion 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 Vermillion common stock outstanding and excludes the effects of 10,144,433 and 7,419,718 potential shares of Vermillion common stock as of March 31, 2019 and 2018, respectively, that are anti-dilutive. Potential shares of Vermillion common stock include incremental shares of Vermillion common stock issuable upon the exercise of outstanding warrants, stock options and unvested restricted stock units.

6. RELATED PARTY TRANSACTIONS

On December 18, 2017, the Company entered into a consulting agreement for a term of up to five months with the Company's former Senior Vice President, Finance and Chief Accounting Officer. Pursuant to the terms of the consulting agreement through May 15, 2018, the consultant provided accounting and finance services related to the transition of financial leadership. The Company agreed to pay $150 per hour for such consulting services. The consultant also remained eligible for payout under the Company's 2017 Corporate Incentive Plan after he satisfactorily met certain performance obligations as outlined in the consulting agreement. During the three months ended March 31, 2019 and 2018, the consultant was paid an aggregate of none and $45,675 for services provided pursuant to the consulting agreement.

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, Vermillion, Inc. ("Vermillion" 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 regarding our business include the following:

- projections or expectations regarding our future test volumes, revenue, cost of revenue, operating expenses, 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;
- our planned business strategy and the anticipated timing of the implementation thereof;
- plans with respect to our market expansion and growth, including plans to market OVA1, OVA1+ and Overa outside the United States;
- plans to develop new algorithms and molecular diagnostic tests;
- plans to develop a product or tool combining an OVA1 with results of a symptom index;
- plans to establish our own payer coverage for Overa 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;
- plans with respect to ASPiRA IVD, Inc. ("ASPiRA IVD");
- our planned focus on the execution of four core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to address unmet medical needs for women faced with gynecologic disease and other conditions and the continued development of our business;
- expectations to increase research and development expenses;
- anticipated efficacy of our products, product development activities and product innovations;
- expected competition in the markets in which we compete;
- plans with respect to ASPiRA LABS, Inc. ("ASPiRA LABS");
- expectations regarding future services provided by Quest Diagnostics Incorporated ("Quest Diagnostics");
- plans to expand our product offerings to additional pelvic disease conditions;
- plans to develop an ethnicity-specific pelvic mass risk assessment;
- plans to launch an offering to detect hereditary breast and ovarian cancer syndrome and carriers of the gene;
- plans regarding the commercialization of Overa;
- plans to develop informatics products and develop and perform laboratory developed tests ("LDTs");
- plans with respect to the Company's pelvic mass registry, including anticipated sources of funding;
- our ability to improve sensitivity and specificity over traditional diagnostic biomarkers;
- expectations regarding existing and future collaborations and partnerships, including OVA1, OVA1+ and Overa distribution agreements;
- plans regarding future publications;
- our continued ability to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests outside the United States;
- our ability to obtain and maintain the regulatory approvals required to market OVA1, OVA1+ and Overa in other countries;
- our continued ability to expand and protect our intellectual property portfolio;
- anticipated liquidity and capital requirements;
- anticipated future losses and our ability to continue as a going concern;
- expectations regarding the second disbursement from our financing arrangement, as amended, with the State of Connecticut Department of Economic and Community Development (the "DECD");
- expected expenditures, including the expected increase in expenses related to sales and marketing of OVA1, OVA1+ and Overa in 2019;
- our ability to use our net operating loss carryforwards;
- anticipated future tax liability under U.S. federal and state income tax legislation;
- expected market adoption of our diagnostic tests, including OVA1, OVA1+ and Overa;
- expectations regarding our ability to launch new products we develop, license, co-market or acquire;

- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations; and
- 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.

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, 2018 (our "2018 Annual Report"), that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including our ability to continue as a going concern; ability to increase the volume of OVA1 or Overa sales; failures by third-party payers to reimburse OVA1 or Overa or changes or variances in reimbursement rates; our ability to secure additional capital on acceptable terms to execute our business plan; our ability to comply with Nasdaq's continued listing requirements to remain publicly traded; in the event that we succeed in commercializing OVA1 and Overa outside the United States, the political, economic and other conditions affecting other countries; our ability to continue developing existing technologies; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; our or our suppliers' ability to comply with Food and Drug Administration ("FDA") requirements for production, marketing and post-market monitoring of our products; additional costs that may be required to make further improvements to our manufacturing operations; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; our ability to continue to develop, protect and promote our proprietary technologies; our ability to use intellectual property directed to diagnose biomarkers; our ability to successfully defend our proprietary technology against third parties; future litigation against us, including infringement of intellectual property and product liability exposure; our ability to retain key employees; business interruptions; 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 comply with FDA regulations that relate to our products and to obtain any FDA clearance or approval required to develop and perform LDTs; ASPiRA IVD's ability to enter into profitable contracts; ASPiRA IVD's ability to maintain effective information systems without significant interruption; and our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances.

Overview

Our vision is to drive the advancement of women's health by providing innovative methods to detect, monitor and manage the treatment of both benign and malignant gynecologic disease.

We expanded our commercial strategy in late 2018 and in the first quarter of 2019 through an investment in our commercial team and the establishment of medical and advisory support and a Key Opinion Leader Network aligned with our territories in the U.S.

We ultimately plan to commercialize OVA1, OVA1+ and Overa on a global level. We currently hold CE marks for OVA1 and Overa. During 2018 we put OVA1 and Overa on a global testing platform, which allows both tests to be deployed worldwide.

We also plan to develop an LDT product series, which we refer to internally as Diagnostic Algorithms #1 ("DxA1") and Diagnostic Algorithms #2 ("DxA2"). We anticipate that DxA1 and DxA2 will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value. In the second half of 2018 and the first quarter of 2019, we reorganized internally and reinvested in a stronger sales and marketing team in order to better position our new commercial offerings.

Our initial product, OVA1, is 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. The FDA cleared OVA1 in September 2009, and we commercially launched OVA1 through Quest Diagnostics in March 2010. In March 2016, we received FDA clearance for a second-generation biomarker panel known as Overa, which is intended to maintain our product's high sensitivity while improving specificity. OVA1 and Overa each use the Roche cobas 4000, 6000 and 8000 platforms.

In June 2014, Vermillion launched ASPiRA LABS, a Clinical Laboratory Improvements Amendments of 1988 ("CLIA") certified national laboratory based in Austin, Texas, 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 diagnostic algorithm to aid in clinical decision making and advance personalized treatment plans. The lab currently processes our OVA1 and Overa tests, and we plan to expand the testing to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPiRA LABS. ASPiRA LABS holds a CLIA Certificate of Registration and a state laboratory license in California, Florida, Maryland, New York, Pennsylvania and Rhode Island. This allows the lab to process OVA1 on a national basis. The Centers for Medicare and Medicaid Services ("CMS") issued a provider number to ASPiRA LABS in March 2015.

In the fourth quarter of 2018, we launched our new generation of technology, OVA1+. OVA1+ was designed to improve accuracy and reduce false elevations in the intermediate risk area by nearly 40% by leveraging the strengths of OVA1's sensitivity and Overa's specificity. It is a combination of OVA1 and Overa, where Overa is used as a confirmation test in the intermediate risk zone. OVA1+ is available through a decentralized platform structure, which will enable hospital networks and super groups to run the test in their labs.

Also in the fourth quarter of 2018, we presented CA125 disparity data at the Mid-Atlantic Gynecologic Oncology Society annual meeting, submitted an abstract to the American Association for Cancer Research and submitted two manuscripts for peer-reviewed publications.

In the first quarter of 2019, we announced that Cigna added OVA1®(MIA) to its national preferred coverage list effective January 15, 2019, adding 15 million lives and bringing the Company's total number of covered lives to 167 million as of March 31, 2019.

Strategy:

We are focused on the execution of four core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to build long-term value for our investors:

- Maximizing the existing OVA1 opportunity in the United States by taking the lead in payer coverage and commercialization of OVA1. This strategy included the launch of a CLIA certified clinical laboratory, ASPiRA LABS, in June 2014, multiple publications, inclusion in the American College of Obstetricians and Gynecologists ("ACOG") adnexal mass guidelines, payer traction and finally the addition of OVA1 to CMS National Fee schedule as of January 2018;
- Expanding the distribution platform beyond the U.S. by launching Overa, a next generation biomarker panel, 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;
- Leveraging our existing database and specimen bank while building the largest specimen and data repository of gynecologic pelvic mass patients worldwide; and
- Expanding our product offerings to additional women's health diseases with a focus on pelvic disease conditions such as endometriosis and polycystic ovarian syndrome ("PCOS") by adding additional gynecologic bio-analytic solutions involving biomarkers, other modalities (*e.g.*, imaging), clinical risk factors and patient data to aid diagnosis and risk stratification of women presenting with a pelvic mass.

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 decentralized international agreement with Overa specimen testing to be performed in the Philippines.

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 October 2016, we launched our pelvic mass specimen and data repository and began the collection of Institutional Review Board patient consents for collection and cataloguing of serum samples for future research purposes.

In November 2016, the ACOG issued Practice Bulletin Number 174 which included OVA1 as a "Multivariate Index Assay". This bulletin outlines ACOG's "new" clinical management guidelines for adnexal mass management.

These new clinical management guidelines replace the July 2007 version, Practice Bulletin Number 83. 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.

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 has now achieved parity with CA125 as a Level B clinical recommendation for the management of adnexal masses.

In September 2017, the preliminary Protecting Access to Medicare Act of 2014 ("PAMA") price for OVA1 and Overa was published by CMS. The preliminary OVA1 rate is based on the median of private payer payments we submitted as part of the market-based payment reforms mandated through PAMA. The Overa price was benchmarked to the only proteomic test currently on the fee schedule, which uses biomarkers and an algorithm to produce a prognostic score. Under the new fee schedule effective January 1, 2018, the price for OVA1 (MIA) (code 81503) is $897 and the price for Overa is $950.

In October 2018, ASPiRA LABS launched OVA1+, a new clinical pathway which combines the strengths of OVA1® and Overa®. The new offering improves accuracy and reduces false elevated risk results by nearly 40%.

In the fourth quarter of 2018, we launched our new platform and cloud service for decentralizing OVA1 testing. The platform and web service will allow other facilities to perform OVA1 and calculate OVA1 scores locally, enabling increased reach and access in the markets we serve.

Recent Developments

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

In May 2019, our first CA125 disparity publication series "Multivariate Index Assay is Superior to CA125 and HE4 Testing in Detection of Ovarian Malignancy in African American Women" was accepted for publication by Biomarkers in Cancer, an international peer-reviewed journal. The research was initiated after the publication of four independent articles showing that African American and non-Caucasian women have lower CA125 levels than Caucasian women. CA125 and HE4 have been used to evaluate women with pelvic masses to determine clinical management. Our review of data from previous prospective studies from ASPiRA Labs revealed that the OVA1 multivariate index assay had superior sensitivity to CA125 and HE4 in detecting ovarian malignancy with marked increases in the African American population. CA125 and HE4 detected only 54.5% of malignancy while OVA1 was able to detect 79.1% in African American women. OVA1 was superior in Caucasian women as well at 93.2% versus 82.9% for CA125 and HE4. This is the first peer reviewed paper on this topic. Our goal is to offer an ethnicity specific pelvic mass risk assessment starting with African American women.

In addition to an ethnicity-specific risk assessment, we are in the development stage of a third generation algorithm. The new test will allow physicians to monitor women with a mass to delay or avoid unnecessary surgery.

In May 2019, we submitted an abstract to the European Society of Gynaecological Oncology, as well as a manuscript to a domestic journal supporting the launch of our test. The test will initially be launched as an LDT, but the prospective monitoring study will be designed to enable us to submit for FDA clearance if we choose to do so.

In June 2019, we intend to launch genetic testing for specific women's health diseases with a core focus on ovarian cancer. Our initial launch will be an offering to detect hereditary breast and ovarian cancer syndrome ("HBOC") and carriers of the gene. Women who test positive for HBOC mutations have a significantly elevated risk of developing ovarian cancer. This complementary product offering will be at the same call point as OVA1+, and, in time, testing results will be reported in a combined report with OVA1+.

Critical Accounting Policies and Estimates

Our product revenue is generated by performing diagnostic services using our OVA1 and Overa tests, and the service is completed upon the delivery of the test result to the prescribing physician. Under the previous revenue recognition accounting methodology, certain product revenue was recognized upon the ultimate receipt of cash. Under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), all revenue is recognized upon completion of the OVA1 or Overa test based on estimates of amounts that will ultimately be realized. In determining the amount to accrue for a delivered test result, we consider factors such as historical payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and us, and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management. We also reviewed our patient account population and determined an appropriate distribution of patient accounts by payer (*i.e.*, Medicare, patient pay, other third-party payer, *etc.*) into portfolios with similar collection experience. When evaluated for collectability, this results in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on an individual contract basis.

Results of Operations - Three Months Ended March 31, 2019 Compared to Three Months Ended March 31, 2018

The selected summary financial and operating data of the Company for the three months ended March 31, 2019 and 2018 were as follows:

	Three Months Ended March 31,		Increase (Decrease)	
(dollars in thousands)	**2019**	**2018**	**Amount**	**%**
Revenue:				
Product	$ 779	$ 613	$ 166	27
Service	24	36	(12)	(33)
Total revenue	803	649	154	24
Cost of revenue:				
Product	516	533	(17)	(3)
Service	178	270	(92)	(34)
Total cost of revenue	694	803	(109)	(14)
Gross profit (loss)	109	(154)	263	171
Operating expenses:				
Research and development	209	142	67	47
Sales and marketing	2,364	1,225	1,139	93
General and administrative	1,255	1,314	(59)	(4)
Total operating expenses	3,828	2,681	1,147	43
Loss from operations	(3,719)	(2,835)	(884)	31
Interest income (expense), net	7	(12)	19	(158)
Other income (expense), net	(4)	(3)	(1)	33
Net loss	$ (3,716)	$ (2,850)	$ (866)	30

Product Revenue. Product revenue was $779,000 for the three months ended March 31, 2019 compared to $613,000 for the same period in 2018. Revenue for ASPiRA LABS is being recognized when the OVA1 test is being performed based on estimates of what we expect to ultimately realize. The 27% product revenue increase is due to an increase in our tests performed.

The number of OVA1 tests performed increased 27% to approximately 2,313 OVA1 tests during the three months ended March 31, 2019 compared to approximately 1,818 OVA1 tests for the same period in 2018. We expect the test volume to improve over the remainder of the year as we continue to realize our sales and marketing investments.

Service Revenue. Service revenue was $24,000 for the three months ended March 31, 2019 compared to $36,000 for the same period in 2018. Service revenue varies from quarter to quarter based on the stages of ongoing customer projects. Revenue for ASPiRA IVD is being recognized once certain revenue recognition criteria have been met (see Note 1 to the financial statements included in Part I, Item I of this Form 10-Q). We expect service revenue to increase slightly in the second quarter of 2019 compared to the first quarter of 2019.

Cost of Revenue - Product. Cost of product revenue was $516,000 for the three months ended March 31, 2019 compared to $533,000 for the same period in 2018, representing a decrease of 3% due primarily to decreases in lab supplies and depreciation and equipment costs, partially offset by increases in postage costs due to new kits, as well as software costs incurred in 2019. We expect the cost of product revenue to increase in the second quarter of 2019 compared to the first quarter of 2019.

Cost of Revenue - Service. Cost of service revenue was $178,000 for the three months ended March 31, 2019 compared to $270,000 for the same period in 2018. The 34% decrease related primarily to lower headcount and lab supplies. We expect the cost of service revenue to fluctuate consistent with service revenue to some extent; however, due to the fixed nature of the costs, we expect the second quarter costs to be largely consistent with those of the first quarter.

Research and Development Expenses. Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses for the three months ended March 31, 2019 increased by $67,000, or 47%, compared to the same period in 2018. This increase was primarily due to purchases required for a study in 2019, partially offset by a reduction in consulting expenses. We expect research and development expenses to increase slightly from the first to the second quarter of 2019 due to expenses in connection with the completion of ongoing studies and publications.

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 and Overa. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the three months ended March 31, 2019 increased $1,139,000, or 93%, compared to the same period in 2018. This increase was primarily due to increased headcount and personnel-related expenses, partially offset by decreased consulting costs in the first quarter of 2019 compared to 2018. We expect sales and marketing expenses to increase modestly over the remainder of 2019 as we focus efforts on the commercialization of OVA1 and Overa.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses and other infrastructure expenses. General and administrative expenses for the three months ended March 31, 2019 decreased by $103,000, or 8%, compared to the same period in 2018. This decrease is primarily due to a decrease in consulting costs in the first quarter of 2019 when compared with those in the first quarter of 2018. We expect general and administrative expenses to remain consistent with the first quarter in the second quarter of 2019.

Liquidity and Capital Resources

We plan to continue to expend resources selling and marketing OVA1, OVA1+ and Overa, operating our IVD trial services business and developing additional diagnostic tests and service capabilities.

We have incurred significant net losses and negative cash flows from operations since inception. At March 31, 2019, we had an accumulated deficit of $410,640,000 and stockholders' equity of $3,637,000. As of March 31, 2019, we had $6,174,000 of cash and cash equivalents and $3,336,000 of current liabilities. The Company expects to incur a net loss in 2019 as well. Working capital levels are not sufficient to fund operations as currently planned through 2019 and beyond, absent a significant increase in revenue over historic revenue or additional financing. Given the above conditions, there is substantial doubt about the Company's ability to continue as a going concern.

On April 17, 2018, the Company completed the Offerings pursuant to which certain investors purchased shares of Vermillion common stock and shares of Vermillion Series B Convertible Preferred Stock for net proceeds of approximately $13,500,000 after deducting offering expenses.

On March 22, 2016, we entered into the Loan Agreement pursuant to which we may borrow up to $4,000,000 from the DECD. Proceeds from the loan were utilized primarily to fund the build-out, information technology infrastructure and other costs related to our Trumbull, Connecticut facility and operations. 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. Under the terms of the agreement, as amended, we may be eligible for forgiveness of up to $2,000,000 of the principal amount of the loan if we achieve certain job creation and retention milestones by March 1, 2021 (the "Measurement Date"). Conversely, if we are either unable to meet these job creation and retention milestones, namely, hiring and retaining for a consecutive two-year period 40 full-time employees with a specified average annual salary by the Measurement Date or do not maintain our Connecticut operations for a period of 10 years, the DECD may require early repayment of a portion or all of the loan depending on job attainment as compared to the required amount plus a penalty of 5% of the total funded loan.

An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The remaining $2,000,000 will be advanced if and when the Company achieves certain other future milestones. The loan may be prepaid at any time without premium or penalty.

We expect to incur a net loss and negative cash flows from operations in 2019. Our management believes that successful achievement of our business objectives may require additional financing.

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

Net cash used in operating activities was $3,108,000 for the three months ended March 31, 2019, resulting primarily from the net loss reported of $3,716,000 and changes in prepaid expenses of $43,000, partially offset by changes in accounts payable, accrued and other liabilities of $261,000, stock compensation expense of $184,000, and depreciation and amortization of $124,000.

Net cash used in operating activities was $2,357,000 for the three months ended March 31, 2018, resulting primarily from the net loss reported of $2,850,000 partially offset by depreciation and amortization of $186,000 stock compensation expense of $182,000 and changes in accounts payable, accrued and other liabilities of $173,000.

Net cash used in investing activities was $48,000 and $24,000 for the three months ended March 31, 2019 and 2018, respectively, which consisted primarily of property and equipment purchases.

Net cash used in financing activities was $30,000 and $55,000 for the three months ended March 31, 2019 and 2018, respectively, which resulted primarily from the principal repayments of the DECD loan.

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, OVA1+ and Overa product adoption by physicians and patients;
- the insurance payer community's acceptance of and reimbursement for OVA1, OVA1+ and Overa;
- the successful targeted launch of Overa and OVA1+;
- resources devoted to our IVD trials laboratory and services;
- the revenue generated by our IVD trial services business;
- our plans to acquire or invest in other products, technologies and businesses; and
- the market price of our common stock.

We have significant net operating loss ("NOL") carryforwards as of March 31, 2019 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, 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, NOLs arising before January 1, 2018 and NOLs arising after January 1, 2018 are subject to different rules. The Company's pre-2018 NOLs will expire in varying amounts from 2023 through 2037, if not utilized, and can offset 100% of future taxable income for regular tax purposes. Any NOLs arising after January 1, 2018 can generally be carried forward indefinitely and can offset up to 80% of future taxable income. The Company's ability to use its NOLs during this period will be dependent on its ability to generate taxable income, and the NOLs could expire before the Company generates sufficient taxable income. The Company's ability to use NOL carryforwards may be restricted due to ownership change limitations occurring in the past or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state specific provisions. These ownership changes may also limit the amount of NOL carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

The Company's management 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 NOL carryforwards before utilization and any NOL carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of 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.

Off-Balance Sheet Arrangements

As of March 31, 2019, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our condensed consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Our senior management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management, including our Chief Executive Officer and Chief Financial Officer, performed an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2019. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2019, our disclosure controls and procedures were effective.

Changes in internal controls over financial reporting.

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

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially and adversely affect our results of operations, cash flows and financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of March 31, 2019, that, in the opinion of management, will have a material adverse effect on our financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors from those disclosed under "Risk Factors" in Part I, Item 1A of our 2018 Annual Report. The risks and uncertainties described in our 2018 Annual Report are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.

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

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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 Designations, Preferences and Rights of Series B Convertible Preferred Stock	8-K	001-34810	4.1	April 17, 2018	
3.4	Fifth Amended and Restated Bylaws of Vermillion, Inc., effective June 19, 2014	10-Q	001-34810	3.3	August 14, 2014	
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					(1)
101	Interactive Data Files					✓

(1) 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.

Vermillion, Inc.

Date: May 14, 2019

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

Date: May 14, 2019

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