VERMILLION, INC.
Form 10-Q
November 10, 2016

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 September 30, 2016

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)

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

As of October 31, 2016, the registrant had 52,268,302 shares of common stock, par value $0.001 per share, outstanding.

VERMILLION, INC.

FORM 10-Q

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PART I - FINANCIAL INFORMATION

ITEM 1.FINANCIAL STATEMENTS

Vermillion, Inc.

Condensed Consolidated Balance Sheets

(Amounts in Thousands, Except Share and Par Value Amounts)

(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 8,080	$ 18,642
Accounts receivable	131	87
Prepaid expenses and other current assets	286	550
Inventories	92	87
Total current assets	8,589	19,366
Property and equipment, net	2,093	1,504
Other assets	-	90
Total assets	$ 10,682	$ 20,960
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 501	$ 988
Accrued liabilities	1,926	2,208
Short-term debt	182	-
Other current liabilities	32	155
Total current liabilities	2,641	3,351
Non-current liabilities:		
Long-term debt	1,704	-
Other non-current liabilities	47	63
Total liabilities	4,392	3,414
Commitments and contingencies (Note 3)		
Stockholders' equity:		

Common stock, par value $0.001 per share, 150,000,000 shares authorized at September 30, 2016 and December 31, 2015; 52,268,302 and 52,113,059 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	52	52
Additional paid-in capital	388,948	388,082
Accumulated deficit	(382,710)	(370,588)
Total stockholders' equity	6,290	17,546
Total liabilities and stockholders' equity	$ 10,682	$ 20,960

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Product	$ 581	$ 330	$ 1,640	$ 1,500
Service	42	-	197	-
License	-	-	-	316
Total revenue	623	330	1,837	1,816
Cost of revenue:				
Product(1)	461	757	1,516	1,822
Service	356	-	416	-
Total cost of revenue	817	757	1,932	1,822
Gross profit	(194)	(427)	(95)	(6)
Operating expenses:				
Research and development(2)	370	874	1,868	2,898
Sales and marketing(3)	1,606	2,462	5,514	7,238
General and administrative(4)	1,295	1,380	4,645	4,111
Total operating expenses	3,271	4,716	12,027	14,247
Loss from operations	(3,465)	(5,143)	(12,122)	(14,253)
Interest income (expense), net	(11)	7	(16)	22
Other income (expense), net	-	(10)	16	99
Net loss	$ (3,476)	$ (5,146)	$ (12,122)	$ (14,132)
Net loss per share - basic and diluted	$ (0.07)	$ (0.10)	$ (0.23)	$ (0.31)
Weighted average common shares used to compute basic and diluted net loss per common share	52,237,287	50,297,031	52,167,543	45,483,889
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$ 27	$ 11	$ 73	$ 30
(2) Research and development	10	44	63	107
(3) Sales and marketing	14	81	70	154
(4) General and administrative	210	409	655	618

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.

Condensed Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (12,122)	$ (14,132)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt	-	(37)
Non-cash license revenue	-	(316)
Depreciation and amortization	523	197
Stock-based compensation expense	861	908
Loss on sale and disposal of property and equipment	3	-
Changes in operating assets and liabilities:		
Accounts receivable	(44)	99
Prepaid expenses and other assets	354	33
Inventories	(5)	(81)
Accounts payable, accrued liabilities and other liabilities	(769)	(278)
Deferred revenue	-	(173)
Net cash used in operating activities	(11,199)	(13,780)
Cash flows from investing activities:		
Purchase of property and equipment	(1,240)	(222)
Net cash used in investing activities	(1,240)	(222)
Cash flows from financing activities:		
Repurchase of common stock	-	(1,291)
Issuance costs related to 2014 private placement	-	(122)
Proceeds from sale of common stock, net of issuance costs	-	17,496
Repayment of short-term debt	-	(1,069)
Proceeds from issuance of DECD loan, net of issuance costs	1,967	-
Principal repayment of DECD loan	(73)	-
Repayment of capital lease obligations	(22)	(5)
Proceeds from issuance of common stock from exercise of stock options	5	2
Net cash provided by financing activities	1,877	15,011
Net increase (decrease) in cash and cash equivalents	(10,562)	1,009
Cash and cash equivalents, beginning of period	18,642	22,965
Cash and cash equivalents, end of period	$ 8,080	$ 23,974
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	24	2
Supplemental disclosure of noncash investing and financing activities:		
Equipment acquired through capital lease agreements	-	107

Changes in other current liabilities related to equipment	-	125

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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") 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™ risk of malignancy test for ovarian cancer ("OVA1"). Until August 2015, the Company distributed OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics") (see Note 2). Since August 2015, the Company has distributed the OVA1 test 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 was formed in April 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. ASPiRA IVD was built around a core of laboratory expertise and a United States Food and Drug Administration ("FDA")-compliant quality system, and strives to deliver accurate and reliable results to its third-party customers suitable for FDA submission.

Going Concern

The Company has incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately $382,710,000 at September 30, 2016. The Company expects to incur a net loss and negative cash flows from operations in the remainder of 2016 and the foreseeable future. The Company's management believes that successful achievement of the Company's business objectives will require additional financing. Given these conditions, there is substantial doubt about the Company's ability to continue as a going concern. The condensed consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

The Company expects to raise capital through a variety of sources, which may include the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and/or public or private debt. 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 its business, results of operations and financial condition.

As discussed in Note 3, on March 22, 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 Loan Agreement provides that the remaining $2,000,000 will be disbursed if and when the Company achieves certain future milestones.

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, 2015 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, 2015, included in Vermillion's Annual Report on Form 10-K which was filed with the Securities and Exchange Commission on March 30, 2016 (the "2015 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

The Company has adopted ASU 2015-03, Simplifying the Presentation of Debt Issuance Costs, for costs incurred in conjunction with the DECD loan (see Note 3). ASU 2015-03 requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability. For public companies, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years.

Revenue Recognition

Product Revenue

The Company has adopted ASC 954-605, Health Care Entities—Revenue Recognition, as revenue from laboratory services has become significant to the Company. The Company's product revenue is generated by performing diagnostic services using its OVA1 test, and the service is completed upon the delivery of test results to the prescribing physician. The Company recognizes revenue related to billings for Medicare and commercial payers on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be realized can be estimated. Until a contract has been negotiated with a commercial payer or governmental program, the OVA1 test may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with the Company that commit them to pay any portion of the cost of the tests in the event that their insurance declines to reimburse the Company. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment from the patient, the related revenue is only recognized upon cash receipt.

Estimates of amounts that the Company will ultimately realize require significant judgment by management. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and the Company may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with the patient’s health plan. Some payers may not cover the OVA1 test as ordered by the prescribing physician under their reimbursement policies. The Company pursues reimbursement from such patients on a case-by-case basis. In the absence of contracted reimbursement coverage or the ability to estimate the amount that will ultimately be realized for the Company's services, revenue is recognized when cash is received.

Service Revenue

The Company's service revenue is generated by performing IVD trial services for third-party customers. In accordance with SAB Topic 13, service revenue is recognized when the following revenue recognition criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

Revenue recognized when cash is received and on an accrual basis for the three and nine months ended September 30, 2016 and 2015 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2016	2015	2016	2015
Quest Diagnostics	$ -	$ 190	$ -	$ 1,282
Cash basis	454	56	1,233	134
Accrual basis	127	84	407	84
IVD trial services (accrual basis)	42	-	197	-
Total	$ 623	$ 330	$ 1,837	$ 1,500

The Company has made no other significant changes in its critical accounting policies and estimates from those disclosed in the 2015 Annual Report.

Recent Accounting Pronouncements

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), Compensation - Stock Compensation. 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 adoption of this standard is not expected to have a material effect on our financial statements.

2. AGREEMENTS WITH QUEST DIAGNOSTICS INCORPORATED

In July 2005, the Company entered into a Strategic Alliance Agreement (as amended, the "Strategic Alliance Agreement") with Quest Diagnostics to develop and commercialize diagnostic tests from the Company's product pipeline. In connection with the Strategic Alliance Agreement, the Company entered into a credit agreement with Quest Diagnostics, pursuant to which Quest Diagnostics provided the Company with a $10,000,000 secured line of

credit to be used to pay for certain costs and expenses related to activities under the Strategic Alliance Agreement. The credit agreement provided for the forgiveness of portions of the amounts borrowed under the secured line of credit upon the achievement of certain milestones related to the development, regulatory approval and commercialization of certain diagnostic tests. Through December 31, 2014, the entire loan was either repaid or forgiven except for $1,106,000 which was in dispute. The dispute regarding the balance of the loan was resolved in March 2015 for a payment to Quest Diagnostics totaling $1,069,000. As a result of this settlement, the Company recognized one-time items during the year ended December 31, 2015, including product revenue of $163,000, license revenue of $202,000, gain on extinguishment of debt of $37,000 and reversal of other liabilities totaling $41,000.

Unrelated to the debt dispute described above, in August 2013, the Company sent Quest Diagnostics a notice of termination of the Strategic Alliance Agreement. Notwithstanding the termination, the Company agreed that Quest Diagnostics could continue to make OVA1 available to healthcare providers on the same financial terms following the termination while negotiating in good faith towards an alternative business structure. Quest Diagnostics disputed the effectiveness of the termination. Prior to the termination, Quest Diagnostics had the non-exclusive right to commercialize OVA1 on a worldwide basis, with exclusive commercialization rights in the clinical reference laboratory marketplace in the United States, India, Mexico, and the United Kingdom through September 2014, with the right to extend the exclusivity period for one additional year.

In March 2015, the Company reached a settlement agreement with Quest Diagnostics that terminated all disputes related to the Strategic Alliance Agreement and the Company's prior loan agreement with Quest Diagnostics. The Company also entered into a new commercial agreement with 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, with the exception of a nominal number of OVA1 tests distributed through Quest Diagnostics after that date. 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, 2017 in exchange for a market value fee. Per the terms of the new commercial agreement, the Company will not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers.

In June 2015, the Company entered into a Share Repurchase Agreement (the "Share Repurchase Agreement") with Quest Diagnostics. Pursuant to the Share Repurchase Agreement, the Company purchased from Quest Diagnostics 860,595 shares of Vermillion common stock for a total purchase price of $1,290,892, or $1.50 per share. The price per share was agreed to in principle in March 2015 and based upon a simple average of the closing prices per share of Vermillion common stock for a trailing 60-day period at that time. This price was then reduced by a negotiated discount. Subsequently, the common stock repurchased from Quest Diagnostics was retired.

3. COMMITMENT AND CONTINGENCIES

Development Loan

On March 22, 2016, the Company entered into the Loan Agreement, 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, 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, 2018. If the Company is unable to meet these job creation and retention milestones within the allotted timeframe 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 plus a penalty of 5%.

An initial disbursement of $2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The Loan Agreement provides that the remaining $2,000,000 will be disbursed if and when the Company achieves certain 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 includes an aggregate annual base rent of $69,000 and annual estimated common area charges, taxes and insurance of $39,000 and expires on May 31, 2017.

In October 2015, the Company entered 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 on January 8, 2016 and a rent abatement period of five months. The lease includes an aggregate annual base rent of $32,000 and annual estimated common area charges, taxes and insurance of $91,000.

Building rent for the three months ended September 30, 2016 and 2015 totaled $71,000 and $48,000, respectively. Building rent for the nine months ended September 30, 2016 and 2015 totaled $175,000 and $141,000, respectively.

Capital Lease

In April 2015, the Company leased a laboratory instrument for a total initial payment of $125,000 and ongoing payments of approximately $3,500 per month for 36 months after delivery. The agreement also requires minimum annual purchases of reagents from the manufacturer of the equipment. The laboratory instrument was placed into service on July 1, 2015.

The accumulated amortization of assets under capital lease obligations was $97,000 and $19,000 as of September 30, 2016 and 2015, respectively. The net book value of assets under capital lease obligations was $135,000 and $213,000 as of September 30, 2016 and 2015, respectively.

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 September 30, 2016 and 2015 totalled $24,000 and $13,000, respectively. Royalty expense for the nine months ended September 30, 2016 and 2015 totalled $66,000 and $60,000, respectively.

4. STOCKHOLDERS' EQUITY

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 8,122,983 shares of Vermillion common stock, subject to adjustment as provided in the 2010 Plan.

Stock-Based Compensation

During the nine months ended September 30, 2016, the Company awarded to Vermillion's non-employee directors 211,000 shares of restricted stock under the 2010 Plan having a fair value of approximately $332,000 as payment for services to be rendered in 2016. These shares of restricted stock vested 50% on June 1, 2016 and 25% on September 1, 2016, and the remaining 25% will vest on December 1, 2016. The Company did not make any awards of restricted stock to non-employee directors during the three months ended September 30, 2016.

During the nine months ended September 30, 2016, the Company also granted certain consultants options to purchase 100,000 shares of Vermillion common stock with an exercise price of $1.64 per share. 50,000 of these stock options vest 25% on each of the four anniversaries of the grant date, and the remaining 50,000 of these stock options have performance-based vesting based on certain metrics through December 31, 2016. The Company also granted certain employees retention options to purchase 35,000 shares of Vermillion common stock with an exercise price of $1.64 per share and retention options to purchase 73,000 shares of Vermillion common stock with an exercise price of $1.37 per share, each of which vest one year from the grant date. The Company also granted certain officers and employees options to purchase approximately 886,000 shares of Vermillion common stock with an exercise price of $1.57 per share. All but 4,000 of these stock options vest 25% on each of the four anniversaries of the grant date. The remaining

4,000 stock options were related to retention and vest fully on February 5, 2017. In addition, the Company granted certain officers and employees options to purchase 250,000 shares of Vermillion common stock with an exercise price of approximately $1.57 per share with performance-based vesting based on certain metrics through December 31, 2016. The Company also granted certain officers and employees options to purchase approximately 120,000 shares of Vermillion common stock with an exercise price of $1.24 per share. These stock options vest 25% on each of the four anniversaries of the vesting commencement date for each such stock option, which is based on the employee start date for new employees and grant date for all other employees.

During the three months ended September 30, 2016, the Company granted an officer options to purchase 125,000 shares of Vermillion common stock with an exercise price of $1.31 per share. These stock options vest 25% on each of the four anniversaries of July 11, 2016. In addition, the Company granted certain employees options to purchase 12,500 shares of Vermillion common stock with an exercise price of $1.35 per share. These stock options vest 25% on each of the four anniversaries of the vesting commencement date for each such stock option.

During the three months ended September 30, 2016, the Company granted certain consultants of the Company options to purchase 120,000 shares of Vermillion common stock with an exercise price of $1.35 per share. These stock options vest in 24 equal monthly installments beginning on the vesting commencement date for each such stock option.

On November 2, 2016, the Company granted an officer options to purchase 50,000 shares of Vermillion common stock with an exercise price of $0.91 per share. These stock options vest 25% on each of the four anniversaries beginning November 1, 2017.

On November 8, 2016, the Company granted a consultant options to purchase 105,000 shares of Vermillion common stock with an exercise price of $0.89 per share. These stock options vest 25% on each of the four anniversaries of the vesting commencement date on November 1, 2016. In addition, the Company granted certain officers and employees options to purchase 560,000 shares of Vermillion common stock with an exercise price of $0.89 per share with performance-based vesting. If the performance metrics are achieved, the options will vest 50% on December 31, 2017 and 50% on December 31, 2018.

The allocation of employee stock-based compensation expense by functional area for the three and nine months ended September 30, 2016 and 2015 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2016	2015	2016	2015
Cost of revenue	$ 24	$ 11	$ 70	$ 30
Research and development	10	44	63	107
Sales and marketing	10	81	66	154
General and administrative	198	406	623	615
Total	$ 242	$ 542	$ 822	$ 906

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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 7,485,632 and 7,972,985 potential shares of Vermillion common stock as of September 30, 2016 and 2015, 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 TRANSACTION

On January 18, 2016, the Company entered into a consulting agreement with David Schreiber, a member of Vermillion's Board of Directors. Pursuant to the terms of the consulting agreement, Mr. Schreiber provided consulting services regarding business strategies and operational plans through the expiration of the agreement on March 31, 2016. During the nine months ended September 30, 2016, Mr. Schreiber was paid $52,000 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 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 ("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 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;
- expected timing of the implementation of our strategy;
- plans with respect to our market expansion and growth, including plans to market Overa outside the United States;
- plans to develop new algorithms and molecular diagnostic tests;
- plans to establish our own payer coverage for OVA1 and Overa;
- 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 to leverage infrastructure and enhance our pipeline of future technologies by fostering relationships with in vitro diagnostic ("IVD") companies;
- plans with respect to ASPiRA IVD, Inc. ("ASPiRA IVD");
- anticipated efficacy of our products, product development activities and product innovations;
- plans with respect to ASPiRA LABS, Inc. ("ASPiRA LABS"), including plans to process the CA 125-II test (which is marketed and sold by a third party) in specific markets;
- plans to expand our ovarian cancer franchise beyond OVA1, including with respect to Overa and OvaX;
- plans regarding the commercialization of Overa;
- plans to develop and perform laboratory development tests ("LDTs");
- plans with respect to the Company's pelvic mass registry, including anticipated sources of funding;
- expectations regarding existing and future collaborations and partnerships;
- anticipated effects on reimbursement for OVA1from changes to Novitas Solutions' administrative requirements;
- 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 with the State of Connecticut Department of Economic and Community Development (the "DECD");
- expected expenditures;
- our ability to use our net operating loss carryforwards; and
- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations.

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, 2015 (our "2015 Annual Report") and our Quarterly Report on Form 10-Q for the three months ended March 31, 2016 (our "2016 First Quarterly 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 increase the volume of OVA1 sales; our ability to market our test through sales channels other than Quest Diagnostics Incorporated ("Quest Diagnostics") including ASPiRA LABS; failures by third-party payers to reimburse OVA1 or changes or variances in reimbursement rates; our ability to secure additional capital on acceptable terms to execute our business plan; our ability to commercialize Overa both within and outside the United States; in the event that we succeed in commercializing Overa outside the United States, the political, economic and other conditions affecting other countries (including foreign exchange rates); 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 United States 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; future litigation against us, including infringement of intellectual property and product liability exposure; our ability to retain key employees; business interruptions; legislative actions resulting in higher compliance costs; changes in healthcare policy; our ability to comply with environmental laws; our ability to generate sufficient demand for ASPiRA LABS' services to cover its operating costs; 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 laboratory-developed tests ("LDTs"); ASPiRA IVD's lack of operating history; ASPiRA IVD's ability to generate and maintain business; fluctuations over time with respect to ASPiRA IVD's operating results; ASPiRA IVD's ability to enter into profitable contracts; ASPiRA IVD's ability to maintain effective information systems without significant interruption; and ASPiRA IVD's ability to perform its services in compliance with contractual requirements, regulatory standards and ethical considerations.

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, with our primary focus being diseases of the female pelvic cavity.

We have expanded our corporate strategy with the goal of transforming Vermillion from a technology license company to a diagnostic service and bio-analytic solutions provider. Our plan is to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders. Our strategy is being deployed in three phases. The three phases are a rebuild phase, which was completed in the third quarter of 2015, a transformation phase, which is ongoing, and a market expansion and growth phase, which we expect to begin in 2017.

During the first phase, we expanded our leadership team by hiring several new senior leaders including a chief executive officer. In addition, we expanded our commercial strategy, re-established medical and advisory support, rebuilt our patient advocacy strategy and established a billing system and a payer strategy outside of our relationship

with Quest Diagnostics. During the second phase, we completed the process of obtaining licensure of ASPiRA LABS in all of the states that require licenses, are in the process of establishing our own payer coverage for OVA1 and plan to launch a second-generation OVA1 test, trademarked Overa. In the third phase, we plan to commercialize Overa by utilizing the full national licensure of ASPiRA LABS, managed care coverage in select markets, our sales force and existing customer base. Unlike OVA1, Overa uses a global testing platform, which will allow Overa to be deployed internationally. In October 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union, and in October 2016, we initiated the targeted launch of Overa in the U.S. with two key accounts converting from OVA1 to Overa. We also plan to develop an LDT product series, which we refer to internally as OvaX. We anticipate that OvaX will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value.

In February 2016, we adopted a plan to streamline our organization. We reduced headcount and other expenses targeting an approximately 20% reduction in go-forward operating expenses in 2016, as compared to operating expenses in 2015.

We are dedicated to the discovery, development and commercialization of novel high-value diagnostic and bio-analytical solutions that help physicians diagnose, treat and improve outcomes for women. Our tests are intended to detect, characterize and stage disease, and to help guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, or to assist in monitoring response to therapy. A distinctive feature of our approach is to combine multiple biomarkers, other modalities and diagnostics, clinical risk factors and patient data into a single, reportable index score that has higher diagnostic accuracy than its constituents. We concentrate on our development of novel diagnostic tests for gynecologic disease, with an initial focus on ovarian cancer. We also intend to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and others through collaborations with leading academic and research institutions.

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 in March 2010. We have completed a second-generation biomarker panel known as Overa, which is intended to maintain our product’s high sensitivity while improving specificity. We submitted our 510(k) clearance application for Overa to the FDA in March 2015, with the goal of commencing the marketing and sale of the panel on a targeted basis in 2016. We received FDA clearance for Overa on March 18, 2016. Overa uses the Roche cobas 6000 platform.

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 test, and we expect the lab to process the CA 125-II test (which is marketed and sold by a third party) in the future in specific markets although we are prohibited from offering CA 125-II tests to existing or future Quest Diagnostics customers (see Note 2 to our third quarter 2016 unaudited financial statements above). We plan to expand the testing provided by ASPiRA LABS 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 & Medicaid Services issued a provider number to ASPiRA LABS in March 2015.

In 2016, we created a new service within the ASPiRA channel strategy, “an ASPiRA IVD Services Program”. In April 2016, we formed ASPiRA IVD to offer IVD trial services to third-party customers. ASPiRA IVD is a specialized laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. ASPiRA IVD was built around a core of laboratory expertise and an FDA-compliant quality system, and strives to deliver accurate and reliable results to its third-party customers suitable

for FDA submission. ASPiRA IVD received a CLIA laboratory license in June 2016 and commenced operations in the second quarter of 2016.

In this program, we also plan to leverage our existing infrastructure and enhance our pipeline of future technologies by fostering relationships with IVD companies who are developing new diagnostics including companion diagnostics platforms. We believe this plan will allow us to continue to be innovative in evaluating potential diagnostics. Our goal with the addition of this line of business is to invest in our short-term and long-term enterprise value while leveraging our specimen bank, database, FDA experience, laboratory informatics and operating efficiency.

Strategy:

We are focused on the execution of five 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;
- Improving OVA1 performance by obtaining FDA clearance of Overa, a next generation biomarker panel while migrating OVA1 to a global testing platform, which we believe may allow for better domestic market penetration and international expansion (FDA clearance was received on March 18, 2016);
- Building an expanded patient base by launching a next generation multi-marker ovarian cancer test (distinct from Overa) to monitor patients at risk for ovarian cancer;
- Expanding our product offerings by adding additional gynecologic bio-analytic solutions involving biomarkers, other modalities (e.g., imaging), clinical risk factors and patient data to aid in the diagnosis and risk stratification of women presenting with a pelvic mass disease; and
- Expanding our customer offerings with the launch of our ASPiRA IVD laboratory services.

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.

OVA1 addresses a clear clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary software cleared as part of the OVA1 510(k) to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary testing, surgery and delayed diagnosis. OVA1 was developed through large pre-clinical studies in collaboration with numerous academic medical centers encompassing over 2,500 clinical samples. OVA1 was fully validated in a prospective multi-center clinical trial encompassing 27 sites reflective of the diverse nature of the clinical centers at which ovarian adnexal masses are evaluated.

In May 2015 we announced that the Company was approved for a product development grant from the Cancer Prevention and Research Institute of Texas (“CPRIT”) for $7,500,000, to help fund the Company's new multi-site pelvic mass registry of patients undergoing evaluation, diagnosis, treatment and follow up for pelvic masses that may lead to gynecological malignancy. Receipt of the grant award was subject to execution of a grant contract with CPRIT. However, the Company and CPRIT were unable to reach mutually agreeable terms on the grant contract and terminated negotiations on August 8, 2016. The Company now intends to fund its pelvic mass registry by utilizing its own resources and pursuing partnerships with third parties.

On April 20, 2016, we announced the publication of the first clinical utility data demonstrating that identification of high-risk patients using OVA1 prior to surgery resulted in referral of nearly all patients who had primary ovarian

malignancies to gynecologic oncologists. The study, titled “The clinical utility of an elevated-risk multivariate index assay score in ovarian cancer patients,” was published in the June 2016 issue of the peer-reviewed journal Current Medical Research & Opinion.

The study surveyed physicians who frequently used OVA1, and identified 122 patients who underwent surgery for a pelvic mass after a high-risk OVA1 score was reported. Of these, 65 had a primary ovarian malignancy, while the remainder were benign or had a metastatic cancer of non-ovarian origin. Pre-surgical involvement of a gynecologic oncologist was documented, including referral, consultation or availability on stand-by; and the specialty of the surgeon who performed the adnexal surgery was also recorded. Of the 4 patients whose surgery was not performed by a gynecologic oncologist, 2 required re-operation for complete staging by a gynecologic oncologist. In comparison, none of the 61 ovarian cancers that were operated on by a gynecologic oncologist required restaging. According to the National Academy of Medicine's 2016 report titled, "," re-operations are common after non-specialists operate on ovarian cancer, and may result in delayed treatment, higher costs and inferior outcomes compared with 'first time right' surgery by a gynecologic oncologist.

In May 2016 we entered into our first international distribution agreement for Overa. Pursuant to this agreement, Bio-Medical Science Co., Ltd. will market and distribute Overa on an exclusive basis in South Korea. Subsequently, we executed exclusive international distribution agreements for Overa with Pro-Genetics LTD in Israel and MacroHealth, Inc. in the Philippines. MacroHealth is Vermillion's first decentralized international agreement with Overa specimen testing to be performed in the Philippines.

In July 2016, as part of our campaign to pursue managed care coverage agreements throughout 2016, we entered into contracts for payer coverage of OVA1 with Priority Health Managed Benefits, a Michigan healthcare insurance company, and Independent Medical Systems, a preferred provider organization based in Dallas, Texas. In August 2016, we announced a contract for payer coverage of OVA1 with Sutter Valley Medical Foundation (d/b/a Gould Medical Foundation), a California network provider. In September 2016, we announced a contract for payer coverage of OVA1 with CareFirst BlueCross BlueShield.

Novitas Solutions, the Medicare contractor that has jurisdiction over claims submitted by Quest Diagnostics for OVA1, covers and reimburses for OVA1. This local coverage determination from Novitas Solutions should essentially provide national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. However, ASPiRA has experienced difficulty in obtaining payment from Novitas Solutions for most claims submitted due to Novitas Solutions' administrative requirements. In October 2016, Novitas Solutions updated its administrative requirements for OVA1 reimbursement. We believe this change will greatly improve our ability to obtain reimbursement for OVA1 from Novitas Solutions.

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 American College of Obstetricians and Gynecologists ("ACOG") issued Practice Bulletin Number 174 which included OVA1 as a "Multivariant 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 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. Guidelines do not exist for Adnexal Masses, only Practice Bulletins. Guidelines do exist, however, for Ovarian Cancer management.

The Practice Bulletin 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 should 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 recommendation for the management of adnexal masses, but OVA1 is the only recommended Level B tool that has FDA clearance for use assessing ovarian cancer risk in adnexal masses.

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Critical Accounting Policies and Estimates

There have been no material changes to our critical accounting policies and estimates from those disclosed in Item 7 of our 2015 Annual Report and in Note 1 in Part I, Item 1 of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.

Results of Operations - Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

The selected summary financial and operating data of the Company for the three months ended September 30, 2016 and 2015 were as follows:

	Three Months Ended September 30,		Increase (Decrease)	
(dollars in thousands)	2016	2015	Amount	%
Revenue:				
Product	$ 581	$ 330	$ 251	76
Service	42	-	42	100
Total revenue	623	330	293	89
Cost of revenue:				
Product	461	757	(296)	(39)
Service	356	-	356	100
Total cost of revenue	817	757	60	8
Gross profit	(194)	(427)	233	(55)
Operating expenses:				
Research and development	370	874	(504)	(58)
Sales and marketing	1,606	2,462	(856)	(35)
General and administrative	1,295	1,380	(85)	(6)
Total operating expenses	3,271	4,716	(1,445)	(31)
Loss from operations	(3,465)	(5,143)	1,678	(33)
Interest income (expense), net	(11)	7	(18)	(257)
Other income (expense), net	-	(10)	10	(100)
Net loss	$ (3,476)	$ (5,146)	$ 1,670	(32)

Product Revenue. Product revenue was $581,000 for the three months ended September 30, 2016 compared to $330,000 for the same period in 2015. For the three months ended September 30, 2016, product revenue was recognized solely from OVA1 tests performed at ASPiRA LABS. Product revenue for the three months ended September 30, 2015 consisted of $190,000 from tests performed by Quest Diagnostics and $140,000 from tests performed at ASPiRA LABS. Revenue for ASPiRA LABS' contractual clients is being recognized when the OVA1 test is performed. All other ASPiRA LABS revenue is being recognized on the cash basis.

The number of OVA1 tests performed decreased 29% to approximately 2,257 OVA1 tests during the three months ended September 30, 2016 compared to approximately 3,183 OVA1 tests for the same period in 2015. All tests for the three months ended September 30, 2016 were performed by ASPiRA LABS. The volume during the three months

ended September 30, 2015 included 1,518 OVA1 tests performed by Quest Diagnostics and 1,665 tests performed by ASPiRA LABS. We attribute the decreased number of tests performed to volume lost after the transition of testing from Quest Diagnostics to ASPiRA LABS in August 2015.

Service Revenue. Service revenue was $42,000 for the three months ended September 30, 2016. There was no service revenue in 2015. Revenue for ASPiRA IVD is being recognized once certain revenue recognition criteria

has been met (see Note 1 to our third quarter 2016 unaudited financial statements above). We expect service revenue to increase modestly in the fourth quarter of 2016.

Cost of Revenue - Product. Cost of product revenue was $461,000 for the three months ended September 30, 2016 compared to $757,000 for the same period in 2015 as one-time costs in 2015 related to the transition of OVA1 testing from Quest Diagnostics to ASPiRA LABS were not repeated in 2016. We expect the cost of product revenue to remain consistent with third quarter 2016 levels in the fourth quarter of 2016.

Cost of Revenue - Service. Cost of service revenue was $356,000 for the three months ended September 30, 2016. There was no cost of service revenue in 2015, as ASPiRA IVD did not commence operations until 2016. We expect the cost of service revenue to remain consistent in the fourth quarter of 2016.

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 also include costs related to activities performed under contracts with our collaborators and strategic partners. Research and development expenses for the three months ended September 30, 2016 decreased $504,000, or 58%, compared to the same period in 2015. This decrease was primarily due to the expiration of our collaboration agreement with The Johns Hopkins University School of Medicine and lower personnel and personnel related expenses due to our February 2016 restructuring and other terminations. We expect research and development expense to remain consistent with third quarter 2016 levels in the fourth quarter of 2016.

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, laboratory personnel and other healthcare professionals regarding OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the three months ended September 30, 2016 decreased $856,000, or 35%, compared to the same period in 2015. This decrease was primarily due to a reduction in personnel and personnel expenses due to our February 2016 restructuring and decreases in consulting services. We expect sales and marketing expenses to decrease from third quarter 2016 levels in the fourth quarter of 2016.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses and other infrastructure expenses. General and administrative expenses for the three months ended September 30, 2016 decreased by $85,000, or 6%, compared to the same period in 2015. The decrease was primarily due to the reduction of personnel-related expenses. We expect general and administrative expenses to remain consistent with third quarter 2016 levels in the fourth quarter of 2016.

Results of Operations - Nine Months Ended September 30, 2016 Compared to Nine Months Ended September 30, 2015

The selected summary financial and operating data of the Company for the nine months ended September 30, 2016 and 2015 were as follows:

	Nine Months Ended September 30,		Increase (Decrease)	
(dollars in thousands)	2016	2015	Amount	%
Revenue:				
Product	$ 1,640	$ 1,500	$ 140	9
Service	197	-	197	100
License	-	316	(316)	(100)
Total revenue	1,837	1,816	21	1
Cost of revenue:				
Product	1,516	1,822	(306)	(17)
Service	416	-	416	100
Total cost of revenue	1,932	1,822	110	6
Gross profit	(95)	(6)	(89)	1,483
Operating expenses:				
Research and development	1,868	2,898	(1,030)	(36)
Sales and marketing	5,514	7,238	(1,724)	(24)
General and administrative	4,645	4,111	534	13
Total operating expenses	12,027	14,247	(2,220)	(16)
Loss from operations	(12,122)	(14,253)	2,131	(15)
Interest income (expense), net	(16)	22	(38)	(173)
Other income, net	16	99	(83)	(84)
Net loss	(12,122)	(14,132)	2,010	(14)

Product Revenue. Product revenue was $1,640,000 for the nine months ended September 30, 2016 compared to $1,500,000 for the same period in 2015. Product revenue for the nine months ended September 30, 2016 consisted of $407,000 from tests performed for ASPiRA LABS' contractual clients and $1,233,000 of revenue recognized based on ASPiRA LABS' cash collections. All product revenue in 2016 was recognized from OVA1 tests performed at ASPiRA LABS. Product revenue for the nine months ended September 30, 2015 consisted of $1,282,000 from tests performed by Quest Diagnostics, including the one-time recognition of $163,000 in deferred product revenue upon the signing of our agreement with Quest Diagnostics in March 2015, $84,000 from tests performed for ASPiRA LABS' contractual clients and $134,000 of revenue recognized based on ASPiRA LABS' cash collections.

The number of OVA1 tests performed decreased 38% to approximately 6,867 OVA1 tests during the nine months ended September 30, 2016 compared to approximately 11,069 OVA1 tests for the same period in 2015. All tests for the nine months ended September 30, 2016 were performed by ASPiRA LABS. The volume during the nine months ended September 30, 2015 included 8,914 OVA1 tests performed by Quest Diagnostics and 2,155 tests performed by ASPiRA LABS. We attribute the decreased number of tests performed to volume lost after the transition of testing from Quest Diagnostics to ASPiRA LABS in August 2015.

Service Revenue. Service revenue was $197,000 for the nine months ended September 30, 2016. There was no service revenue in 2015. Revenue for ASPiRA IVD is being recognized once certain revenue recognition criteria has been met (see Note 1 to our third quarter 2016 unaudited financial statements above).

Cost of Revenue - Product. Cost of product revenue was $1,516,000 for the nine months ended September 30, 2016 compared to $1,822,000 for the same period in 2015. The decrease in cost of product revenue was due to one-time items in 2015 related to the transition of OVA1 testing from Quest Diagnostics to ASPiRA LABS not being repeated in 2016.

Cost of Revenue - Service. Cost of service revenue was $416,000 for the nine months ended September 30, 2016. There was no cost of service revenue in 2015 as ASPiRA IVD was not formed until 2016.

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 also include costs related to activities performed under contracts with our collaborators and strategic partners. Research and development expenses decreased by $1,030,000, or 36%, for the nine months ended September 30, 2016 compared to the same period in 2015. This decrease was primarily due to a decrease in costs associated with our collaboration with The Johns Hopkins University School of Medicine as well as lower personnel and related costs due to lower headcount.

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, laboratory personnel and other healthcare professionals regarding OVA1. 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 decreased by $1,724,000, or 24%, for the nine months ended September 30, 2016 compared to the same period in 2015. This decrease was primarily due to a reduction in personnel and personnel expenses due to our February 2016 restructuring and decreases in customer seminars and managed markets study costs.

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 increased by $534,000, or 13%, for the nine months ended September 30, 2016 compared to the same period in 2015. The increase was primarily due to $469,000 of charges incurred in connection with opening the ASPiRA IVD laboratory and $82,000 of increased consulting costs associated with international business development, partially offset by a reduction in personnel expenses.

Other Income (Expense), Net. Net other income was $16,000 for the nine months ended September 30, 2016 compared to $99,000 in the same period in 2015. Other income for the nine months ended September 30, 2015 related to recognition of one-time items related to the March 2015 agreement with Quest Diagnostics.

Liquidity and Capital Resources

We plan to continue to expend resources selling and marketing 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 September 30, 2016, we had an accumulated deficit of $382,710,000 and stockholders' equity of $6,290,000. As of September 30, 2016, we had $8,080,000 of cash and cash equivalents and $2,641,000 of current liabilities. Working capital was $5,948,000 and $16,015,000 at September 30, 2016 and December 31, 2015, respectively.

On March 22, 2016, we entered into an agreement pursuant to which we may borrow up to $4,000,000 from the DECD. We received an initial disbursement of $2,000,000 on April 15, 2016 under this agreement. The remaining

$2,000,000 will be disbursed if and when we achieve certain future milestones.

We expect to incur a net loss and negative cash flows from operations in the remainder of 2016 and the foreseeable future. Our management believes that successful achievement of our business objectives will require additional financing. Given these conditions, there is substantial doubt about our ability to continue as a going

concern. The condensed consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

We expect to raise capital through a variety of sources, which may include the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and/or public or private debt. However, additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may not be able to continue sales and marketing, research and development, or other operations on the scope or scale of current activity and that could have a material adverse effect on our business, results of operations and financial condition.

Net cash used in operating activities was $11,199,000 for the nine months ended September 30, 2016 resulting primarily from the net loss reported of $12,122,000 and changes in accounts payable, accrued and other liabilities of $769,000 partially offset by stock compensation expense of $861,000, depreciation and amortization of $523,000 and prepaid expenses of $354,000.

Net cash used in operating activities was $13,780,000 for the nine months ended September 30, 2015 resulting primarily from the net loss reported of $14,132,000 and non-cash license revenue of $316,000, partially offset by stock compensation expense of $908,000.

Net cash used in investing activities was $1,240,000 and $222,000 for the nine months ended September 30, 2016 and 2015, respectively. The costs in 2016 resulted from purchases of property and equipment for the ASPiRA IVD laboratory and also included a $125,000 down payment on the Roche cobas 6000 analyzer used at ASPiRA LABS.

Net cash provided by financing activities was $1,877,000 for the nine months ended September 30, 2016, which consisted primarily of proceeds from the DECD loan.

Net cash provided by financing activities was $15,011,000 for the nine months ended September 30, 2015. The cash provided by financing activities consisted primarily of proceeds from the sale of common stock of $17,496,000 in July 2015, partially offset by the repurchase of common stock from Quest Diagnostics, in the amount of $1,291,000, the repayment of short-term debt of $1,069,000 to Quest Diagnostics and $122,000 of offering expenses relating to our December 2014 private placement.

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

- resources devoted to sales, marketing and distribution capabilities;
- the rate of product adoption by physicians and patients;
    - the insurance payer community’s acceptance of and reimbursement for OVA1 and Overa;
- the successful launch of Overa;
- resources devoted to our IVD trials laboratory and services;
- the successful launch of 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 September 30, 2016 for which a full valuation allowance has been provided due to our history of operating losses. Our ability to use our net NOL credit 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, as well as similar state provisions. 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.

In connection with a private placement offering of common stock and warrants we completed in May 2013, we entered into a stockholders agreement which, among other things, gives two of the primary investors in that

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

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

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

Off-Balance Sheet Arrangements

As of September 30, 2016, 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, information 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 Accounting Officer, performed an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2016. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of September 30, 2016, our disclosure controls and procedures were effective.

Changes in internal controls over financial reporting.

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

PART II - OTHER INFORMATION

ITEM 1.LEGAL PROCEEDINGS

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially and adversely affect our results of operations, cash flows and financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of September 30, 2016, 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 2015 Annual Report and 2016 First Quarterly Report. The risks and uncertainties described in our 2015 Annual Report and 2016 First Quarterly 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

(a) 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	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 Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√
32.1	Certification of the Chief Executive Officer and Chief Accounting 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: November 10, 2016 /s/ Valerie B. Palmieri
Valerie B. Palmieri

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 10, 2016 /s/ Eric J. Schoen
Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)