VERMILLION, INC.
Form 10-Q
August 11, 2017

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 June 30, 2017

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, 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. (Check one):

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

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 July 31, 2017, the registrant had 56,164,082 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)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 6,028	$ 5,242
Accounts receivable	214	275
Prepaid expenses and other current assets	269	498
Inventories	102	93
Total current assets	6,613	6,108
Property and equipment, net	1,549	1,911
Other assets	11	-
Total assets	$ 8,173	$ 8,019
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 300	$ 881
Accrued liabilities	1,541	1,464
Short-term debt	188	182
Other current liabilities	32	34
Total current liabilities	2,061	2,561
Non-current liabilities:		
Long-term debt	1,538	1,667
Other non-current liabilities	47	29
Total liabilities	3,646	4,257
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at		

June 30, 2017 and December 31, 2016; 56,164,082 and 52,328,492 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	56	52
Additional paid-in capital	395,060	389,266
Accumulated deficit	(390,589)	(385,556)
Total stockholders' equity	4,527	3,762
Total liabilities and stockholders' equity	$ 8,173	$ 8,019

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Product	$ 860	$ 554	$ 1,538	$ 1,059
Service	38	155	86	155
Total revenue	898	709	1,624	1,214
Cost of revenue:(1)				
Product	428	527	850	1,055
Service	266	60	571	60
Total cost of revenue	694	587	1,421	1,115
Gross profit	204	122	203	99
Operating expenses:				
Research and development(2)	268	564	493	1,498
Sales and marketing(3)	1,041	1,628	2,064	3,908
General and administrative(4)	1,241	1,691	2,648	3,350
Total operating expenses	2,550	3,883	5,205	8,756
Loss from operations	(2,346)	(3,761)	(5,002)	(8,657)
Interest income (expense), net	(10)	(8)	(22)	(5)
Other income (expense), net	(4)	20	(9)	16
Net loss	$ (2,360)	$ (3,749)	$ (5,033)	$ (8,646)
Net loss per share - basic and diluted	$ (0.04)	$ (0.07)	$ (0.09)	$ (0.17)
Weighted average common shares used to compute basic and diluted net loss per common share	56,113,917	52,151,440	55,123,977	52,132,288
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$ 40	$ 22	$ 79	$ 46
(2) Research and development	2	22	5	53
(3) Sales and marketing	40	14	77	56
(4) General and administrative	295	319	510	445

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.

Condensed Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (5,033)	$ (8,646)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	401	323
Stock-based compensation expense	671	600
Loss on sale and disposal of property and equipment	4	3
Changes in operating assets and liabilities:		
Accounts receivable	61	(156)
Prepaid expenses and other assets	218	233
Inventories	(9)	7
Accounts payable, accrued liabilities and other liabilities	(504)	(835)
Deferred revenue	-	16
Net cash used in operating activities	(4,191)	(8,455)
Cash flows from investing activities:		
Purchase of property and equipment	(43)	(1,054)
Net cash used in investing activities	(43)	(1,054)
Cash flows from financing activities:		
Proceeds from private placement offering of common stock, net of issuance costs	5,127	-
Proceeds from issuance of DECD loan, net of issuance costs	-	1,966
Principal repayment of DECD loan	(92)	(28)
Repayment of capital lease obligations	(15)	(14)
Proceeds from issuance of common stock from exercise of stock options	-	5
Net cash provided by financing activities	5,020	1,929
Net increase (decrease) in cash and cash equivalents	786	(7,580)
Cash and cash equivalents, beginning of period	5,242	18,642
Cash and cash equivalents, end of period	$ 6,028	$ 11,062
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	24	10

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," "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.

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 $390,589,000 at June 30, 2017. The Company also expects to incur a net loss and negative cash flows from operations for the remainder of 2017. 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 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 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 in April 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, 2016 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, 2016, included in Vermillion's Annual Report on Form 10-K which was filed with the Securities and Exchange Commission on March 31, 2017 (the "2016 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

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 and Overa tests, 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 and Overa tests 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 and Overa tests 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.

See discussion of FASB ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASU No. 2014-09”) included in Recent Accounting Pronouncements below.

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.

See discussion of ASU No. 2014-09 included in Recent Accounting Pronouncements below.

The Company has made no other significant changes in its critical accounting policies and estimates from those disclosed in the 2016 Annual Report.

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 adoption of this standard is not expected to have a material effect on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. This guidance requires that an entity depict the consideration by applying a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On April 1, 2015, the FASB voted for a one-year deferral of the effective date of the new revenue recognition standard, ASU No. 2014-09. On July 15, 2015, the FASB affirmed these changes, which requires public entities to apply the amendments in ASU 2014-09 for annual reporting beginning after December 15, 2017. Early adoption is permitted beginning after December 31, 2016, the original effective date in ASU 2014-09.

The Company is in the early stages of its analysis of the effect ASU 2014-09 will have on its Service Revenue, but expects to complete its analysis during the second half of 2017.

The Company is also in the early stages of its analysis of the effect ASU 2014-09 will have on its Product Revenue and also expects to complete this analysis in the second half of 2017. Revenue that is recognized upon the ultimate receipt of cash under the Company's existing revenue recognition policy will have to be reassessed under the new standard. The next step in the Company's implementation process is to review its patient account population to determine the appropriate distribution of patient accounts by payer (i.e., Medicare, patient pay, other third-party

payer, etc.) into portfolios with similar collection experience that, when evaluated for collectability, will result in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on a contract-by-contract basis.

The Company has not yet determined if it plans to utilize the full retrospective or modified retrospective method of adoption, but anticipates adopting the new standard in the first quarter of 2018.

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 11, 2017, Quest Diagnostics has agreed to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing through at least March 11, 2018 in exchange for a market value fee. Per the terms of this agreement, the Company will not offer to existing or future Quest Diagnostics customers tests that Quest Diagnostics offers.

3. COMMITMENTS 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 $2,000,000 April 2016 initial disbursement under the Loan Agreement 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. Conversely, if the Company is unable to meet these job creation milestones, namely, hiring 40 full time employees with a specified average annual salary within the allotted timeframe and retaining those employees for a two-year period 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%.

As discussed above, 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 $85,000 and annual estimated common area charges, taxes and insurance of $46,000 and expires on January 31, 2019.

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 in January 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 $95,000.

Building rent for the three months ended June 30, 2017 and 2016 totaled $62,000 and $53,000, respectively. Building rent for the six months ended June 30, 2017 and 2016 totaled $123,000 and $104,000, 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 $155,000 and $77,000 as of June 30, 2017 and 2016, respectively. The net book value of assets under capital lease obligations was $77,000 and $155,000 as of June 30, 2017 and 2016, 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 June 30, 2017 and 2016 totalled $34,000 and $22,000, respectively. Royalty expense for the six months ended June 30, 2017 and 2016 totalled $63,000 and $42,000, respectively.

4. 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 may be exercised from time to time beginning August 17, 2017 and 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 $4,296,000.

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

Stock-Based Compensation

During the six months ended June 30, 2017, the Company awarded to Vermillion's non-employee directors 131,250 shares of restricted stock under the 2010 Plan having a fair value of approximately $281,000 as payment for services to be rendered in 2017. These shares of restricted stock vested 50% on June 1, 2017, and will vest 25% on each of September 1, 2017 and December 1, 2017. The Company also issued to certain consultants 22,841 shares of restricted stock under the 2010 Plan having a fair value of approximately $39,000.

During the three months ended June 30, 2017, the Company issued to certain consultants 9,213 shares of restricted stock under the 2010 Plan having a fair value of approximately $19,000. The Company did not make any awards of restricted stock to non-employee directors during the three months ended June 30, 2017.

During the six months ended June 30, 2017, the Company also granted certain consultants options to purchase 70,000 shares of Vermillion common stock with an exercise price of $2.14 per share. The Company also granted certain officers and employees options to purchase approximately 916,000 shares of Vermillion common

stock with an exercise price of $2.14 per share. These stock options generally vest 25% on each of the four anniversaries of the grant date. 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 $2.14 per share with performance-based vesting based on certain metrics through December 31, 2017. These options vest 25% on each of the four anniversaries of the grant date if the performance-based metrics are met.

During the three months ended June 30, 2017, the Company granted certain officers and employees options to purchase 14,500 shares of Vermillion common stock with an exercise price of $1.83 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 and six months ended June 30, 2017 and 2016 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2017	2016	2017	2016
Cost of revenue	$ 20	$ 22	$ 40	$ 46
Research and development	2	22	5	53
Sales and marketing	38	14	70	56
General and administrative	283	320	414	425
Total	$ 343	$ 378	$ 529	$ 580

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 11,662,280 and 7,808,044 potential shares of Vermillion common stock as of June 30, 2017 and 2016, 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.

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 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 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 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");
- expected service revenue growth based on ASPiRA IVD;
- expected license revenue in future periods;
- our planned focus on the execution of five 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;
- 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 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;
- anticipated effects on reimbursement for OVA1 from changes to Novitas Solutions' administrative requirements;
- expectations regarding the Company's monitoring and combining multiple protein biomarkers to create diagnostic tests to aid physicians considering treatment options for patients with complex diseases, and the Company's future development of new In Vitro Diagnostic Multivariate Index Assays (IVDMIA);
- expectations regarding existing and future collaborations and partnerships, including 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 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 with the State of Connecticut Department of Economic and Community Development (the "DECD");
- expected expenditures, including the expected decrease in expenses related to research and development in 2017;
- our ability to use our net operating loss carryforwards;
- expected market adoption of our diagnostic tests, including OVA1 and Overa;
- expectations regarding our ability to launch new products developed, licensed, co-marketed or acquired;
- 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, 2016 (our "2016 Annual Report") and Part II, Item 1A. "Risk Factors" of our Quarterly Report on Form 10-Q for the three months ended March 31, 2017 (our "2017 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 or Overa 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 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 commercialize OVA1 and/or Overa both within and outside the United States; in the event that we succeed in commercializing OVA1 and/or 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; ASPiRA IVD's ability to perform its services in compliance with contractual requirements, regulatory standards and ethical considerations; and our ability to continue as a going concern..

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 now virtually complete except for continuing expansion of payer coverage, and a market expansion and growth phase, which we expect to begin in the near future.

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, reestablished 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, Multivariate Index Assay (MIA), and launched a second-generation OVA1 test, trademarked Overa, Multivariate Index Assay, 2nd Generation (MIA2G), on a targeted basis. In the third phase, we plan to fully commercialize OVA1 and Overa by utilizing the full national licensure of ASPiRA LABS, select laboratories for distribution, 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. We initiated the targeted launch of Overa in October 2016 with two key accounts converting from OVA1 to Overa. In October 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union. 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.

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 launched on a targeted basis a second-generation biomarker panel known as Overa, which is intended to maintain our product's high sensitivity while improving specificity. We received FDA clearance for Overa in March 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 and Overa tests, and we plan to develop and perform LDTs at ASPiRA LABS in the future. ASPiRA LABS holds a CLIA Certificate of Registration and a state laboratory license in California, Maryland, New York, Pennsylvania and Rhode Island. Our Florida license is in process of renewal, which is expected shortly. 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 specificity and expanding the distribution platform by launching Overa, a next generation biomarker panel, on a targeted basis 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 (FDA clearance for Overa was received in March 2016);
- Leveraging our existing database and specimen bank while building the largest specimen and data repository of gynecologic pelvic mass patients worldwide;
- Expanding our product offerings to additional pelvic disease conditions such as endometriosis and polycystic ovarian syndrome 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 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.

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 LABS initially 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 which has improved 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 "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 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 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 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.

In December 2016, we received an FDA Clarification Letter regarding OVA1 and Overa. This letter was in reference to the September 7, 2016 FDA Safety Communication advising women and their physicians against the use of ovarian cancer screening tests for asymptomatic women.

In order to avoid any confusion, as well as to document the FDA position on OVA1 and Overa, Jeffrey Shuren, M.D., J.D., Director for the Center for Devices and Radiological Health at the FDA, sent a letter to Vermillion, dated December 21, 2016. In the letter, Dr. Shuren stated:

We agree that this safety communication does not apply to Vermillion's FDA-cleared tests, OVA1 (MIA) and Overa (MIA2G), which are not screening tests for ovarian cancer.

FDA cleared OVA1 (MIA) and Overa (MIA2G) as aids to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The intended uses of the two assays are the same—to help physicians more reliably identify which patients would benefit from consultation with or referral to a gynecologic oncologist. OVA1 (MIA) and Overa (MIA2G) are indicated for women who present with an adnexal mass.

In March 2015, we 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 10, 2015. Pursuant to this agreement, as amended as of March 11, 2017, Quest Diagnostics has agreed to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing through at least March 11, 2018 in exchange for a market value fee. Per the terms of this agreement, we will not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers.

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 2016 Annual Report.

Results of Operations - Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

The selected summary financial and operating data of the Company for the three months ended June 30, 2017 and 2016 were as follows:

	Three Months Ended June 30,		Increase (Decrease)	
(dollars in thousands)	2017	2016	Amount	%
Revenue:				
Product	$ 860	$ 554	$ 306	55
Service	38	155	(117)	(75)
Total revenue	898	709	189	27
Cost of revenue:				
Product	428	527	(99)	(19)
Service	266	60	206	343
Total cost of revenue	694	587	107	18
Gross profit	204	122	82	67
Operating expenses:				
Research and development	268	564	(296)	(52)
Sales and marketing	1,041	1,628	(587)	(36)
General and administrative	1,241	1,691	(450)	(27)
Total operating expenses	2,550	3,883	(1,333)	(34)
Loss from operations	(2,346)	(3,761)	1,415	(38)
Interest income (expense), net	(10)	(8)	(2)	25
Other income (expense), net	(4)	20	(24)	(120)
Net loss	(2,360)	(3,749)	1,389	(37)

Product Revenue. Product revenue was $860,000 for the three months ended June 30, 2017 compared to $554,000 for the same period in 2016. Revenue for ASPiRA LABS is being recognized when the OVA1 test is being performed or when amounts that will ultimately be realized can be estimated. All other ASPiRA LABS revenue is being recognized

on a cash basis and thus recognition of revenue lags the performance of some OVA1 tests. The 55% product revenue growth is due to improvement in the average unit price received per test compared to the same quarter in the prior year. The increase in average unit price was driven by an increase in client bill contracts, expansion of positive medical policy and contracting with payers, and improved billing and collection practices.

The number of OVA1 tests performed increased 3% to approximately 2,418 OVA1 tests during the three months ended June 30, 2017 compared to approximately 2,345 OVA1 tests for the same period in 2016. We expect test volume and, to a lesser extent, product revenue to decrease in the third quarter of 2017 due primarily to the loss of one client bill customer and also some summer seasonality. We expect the direct volume loss from the client bill customer to be between 5% and 10% in the third quarter relative to volume in the second quarter of 2017.

Service Revenue. Service revenue was $38,000 for the three months ended June 30, 2017 compared to $155,000 for the same period in 2016, a decrease of 75%. Service revenue will vary from quarter to quarter based on the size of ongoing customer projects. Revenue for ASPiRA IVD is being recognized once certain revenue recognition criteria has 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 in the third quarter of 2017.

Cost of Revenue - Product. Cost of product revenue was $428,000 for the three months ended June 30, 2017 compared to $527,000 for the same period in 2016, representing a decrease of 19% due to operating efficiencies compared to the prior year quarter. We expect the cost of product revenue to remain consistent with second quarter 2017 levels in the third quarter of 2017.

Cost of Revenue - Service. Cost of service revenue was $266,000 for the three months ended June 30, 2017 compared to $60,000 for the same period in 2016. ASPiRA IVD did not commence operations until June 2016 and thus the second quarter of 2016 included only one month of expense compared to a full quarter of expense in 2017. We expect the cost of service revenue to remain consistent with second quarter 2017 levels in the third quarter of 2017.

Research and Development Expenses. Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses for the three months ended June 30, 2017 decreased $296,000, or 52%, compared to the same period in 2016. This decrease was primarily due to a reduction in personnel and personnel related expenses due to the clearance of Overa in March 2016. We expect research and development expenses to remain consistent with second quarter 2017 levels in the third quarter of 2017.

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 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 June 30, 2017 decreased $587,000, or 36%, compared to the same period in 2016. This decrease was primarily due to a reduction in personnel and personnel expenses and decreases in consulting and marketing services. We expect sales and marketing expenses to increase modestly over the remainder of 2017 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 June 30, 2017 decreased by $450,000, or 27%, compared to the same period in 2016. The decrease was primarily due to the reduction of consulting services and ASPiRA IVD start-up expenses in 2016 not being repeated in 2017. We expect general and administrative expenses to remain consistent with second quarter 2017 levels in the third quarter of 2017.

Results of Operations – Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

The selected summary financial and operating data of the Company for the six months ended June 30, 2017 and 2016 were as follows:

	Six Months Ended June 30,		Increase (Decrease)	
(dollars in thousands)	2017	2016	Amount	%
Revenue:				
Product	$ 1,538	$ 1,059	$ 479	45
Service	86	155	(69)	(45)
License	-	-	-	-
Total revenue	1,624	1,214	410	34
Cost of revenue:				
Product	850	1,055	(205)	(19)
Service	571	60	511	852
Total cost of revenue	1,421	1,115	306	27
Gross profit	203	99	104	105
Operating expenses:				
Research and development	493	1,498	(1,005)	(67)
Sales and marketing	2,064	3,908	(1,844)	(47)
General and administrative	2,648	3,350	(702)	(21)
Total operating expenses	5,205	8,756	(3,551)	(41)
Loss from operations	(5,002)	(8,657)	3,655	(42)
Interest income (expense), net	(22)	(5)	(17)	340
Other income (expense), net	(9)	16	(25)	(156)
Net loss	(5,033)	(8,646)	3,613	(42)

Product Revenue. Product revenue was $1,538,000 for the six months ended June 30, 2017 compared to $1,059,000 for the same period in 2016. Revenue for ASPiRA LABS is being recognized when the OVA1 test is being performed or when amounts that will ultimately be realized can be estimated. All other ASPiRA LABS revenue is being recognized on a cash basis and thus recognition of revenue lags the performance of some OVA1 tests. The 45% product revenue growth is due to improvement in the average unit price received per test compared to the same quarter in the prior year. The increase in average unit price was driven by an increase in client bill contracts, expansion of positive medical policy and contracting with payers, and improved billing and collection practices.

The number of OVA1 tests performed increased 2% to approximately 4,711 OVA1 tests during the six months ended June 30, 2017 compared to approximately 4,610 OVA1 tests for the same period in 2016.

Service Revenue. Service revenue was $86,000 for the six months ended June 30, 2017 compared to $155,000 for the same period in 2016, a decrease of 45%. Service revenue will vary from quarter to quarter based on the size of ongoing customer projects. Revenue for ASPiRA IVD is being recognized once certain revenue recognition criteria has been met (see Note 1 to the financial statements included in Part I, Item I of this Form 10-Q).

Cost of Revenue - Product. Cost of product revenue was $850,000 for the six months ended June 30, 2017 compared to $1,055,000 for the same period in 2016, representing a decrease of 19% due to operating efficiencies compared to the prior year.

Cost of Revenue - Service. Cost of service revenue was $571,000 for the six months ended June 30, 2017 compared to $60,000 for the same period in 2016. ASPiRA IVD did not commence operations until June 2016 and thus included only one month of expense compared to two full quarters of expense in 2017.

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 through March 2016 also included costs related to activities performed under contracts with our collaborators and strategic partners. Research and development expenses for the six months ended June 30, 2017 decreased $1,005,000, or 67%, compared to the same period in 2016. This decrease was primarily due to the expiration of our collaboration agreement with The Johns Hopkins University School of Medicine in March 2016 as well as lower personnel and personnel related expenses due to the clearance of Overa in March 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 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 six months ended June 30, 2017 decreased $1,844,000, or 47%, compared to the same period in 2016. This decrease was primarily due to a reduction in personnel and personnel expenses and decreases in consulting and marketing services compared to the prior year period.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses and other infrastructure expenses. General and administrative expenses for the six months ended June 30, 2017 decreased by $702,000, or 21%, compared to the same period in 2016. The decrease was primarily due to the reduction of consulting services and ASPiRA IVD start-up expenses in 2016 not being repeated in 2017.

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 June 30, 2017, we had an accumulated deficit of $390,589,000 and stockholders' equity of $4,527,000. As of June 30, 2017, we had $6,028,000 of cash and cash equivalents and $2,061,000 of current liabilities. Working capital was $4,552,000 and $3,547,000 at June 30, 2017 and December 31, 2016, respectively.

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.

In March 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 in April 2016 under this agreement. The remaining $2,000,000 will be disbursed if and when we achieve certain future milestones. See Note 3 to the financial statements included in Part I, Item I of this Form 10-Q for information regarding such milestones.

We expect to incur a net loss and negative cash flows from operations in the remainder of 2017. 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.

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.

Net cash used in operating activities was $4,191,000 for the six months ended June 30, 2017, resulting primarily from the net loss reported of $5,033,000 and changes in accounts payable, accrued and other liabilities of $504,000 partially offset by stock compensation expense of $671,000, depreciation and amortization of $401,000 and prepaid expenses of $218,000.

Net cash used in operating activities was $8,455,000 for the six months ended June 30, 2016 resulting primarily from the net loss reported of $8,646,000 and changes in accounts payable, accrued and other liabilities of $835,000 partially offset by stock compensation expense of $600,000 and depreciation and amortization of $323,000.

Net cash used in investing activities was $43,000 and $1,054,000 for the six months ended June 30, 2017 and 2016, respectively. The costs in 2016 resulted from purchases of property and equipment for the ASPiRA IVD laboratory.

Net cash provided by financing activities was $5,020,000 for the six months ended June 30, 2017, which consisted primarily of proceeds from the sale of Vermillion common stock in our February 2017 private placement, net of issuance costs.

Net cash provided by financing activities of $1,929,000 for the six months ended June 30, 2016 consisted primarily of proceeds from 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 and Overa product adoption by physicians and patients;
- the insurance payer community's acceptance of and reimbursement for OVA1 and Overa;
- the successful targeted launch of Overa;
- 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 June 30, 2017 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.

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 June 30, 2017, 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 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 June 30, 2017. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of June 30, 2017, 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.

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PART II - OTHER INFORMATION

ITEM 1.LEGAL PROCEEDINGS

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially and adversely affect our results of operations, cash flows and financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of June 30, 2017, 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 2016 Annual Report and Part II, Item 1A of our 2017 First Quarterly Report. The risks and uncertainties described in our 2016 Annual Report and 2017 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: August 11, 2017 /s/ Valerie B. Palmieri
Valerie B. Palmieri

President and Chief Executive Officer

(Principal Executive Officer)

Date: August 11, 2017 /s/ Eric J. Schoen
Eric J. Schoen

Senior Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)