VERMILLION, INC.
Form 10-Q
May 16, 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 March 31, 2016

OR

TRANSITION REPORT UNDER 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 April 30, 2016, the registrant had 52,116,600 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)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 13,067	$ 18,642
Accounts receivable	117	87
Prepaid expenses and other current assets	676	550
Inventories	71	87
Total current assets	13,931	19,366
Property and equipment, net	1,933	1,504
Other assets	8	90
Total assets	$ 15,872	$ 20,960
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 672	$ 988
Accrued liabilities	2,112	2,208
Other current liabilities	156	155
Total current liabilities	2,940	3,351
Lease obligation - long term	55	63
Total liabilities	2,995	3,414
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at March 31, 2016 and December 31, 2015; 52,116,600 and 52,113,059 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	52	52

Additional paid-in capital	388,310	388,082
Accumulated deficit	(375,485)	(370,588)
Total stockholders' equity	12,877	17,546
Total liabilities and stockholders' equity	$ 15,872	$ 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 March 31,	
	2016	2015
Revenue:		
Product	$ 505	$ 635
License	-	316
Total revenue	505	951
Cost of revenue:		
Product(1)	528	491
Gross profit (loss)	(23)	460
Operating expenses:		
Research and development(2)	934	1,105
Sales and marketing(3)	2,280	2,217
General and administrative(4)	1,659	1,400
Total operating expenses	4,873	4,722
Loss from operations	(4,896)	(4,262)
Interest income	3	9
Other income (expense), net	(4)	116
Net loss	$ (4,897)	$ (4,137)
Net loss per share - basic and diluted	$ (0.09)	$ (0.10)
Weighted average common shares used to compute basic and diluted net loss per common share	52,113,137	43,115,790
Non-cash stock-based compensation expense included in operating expenses:		
(1) Cost of revenue	$ 24	$ 9
(2) Research and development	31	31
(3) Sales and marketing	42	37
(4) General and administrative	126	88

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.

Condensed Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (4,897)	$ (4,137)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt	-	(78)
Non-cash license revenue	-	(316)
Depreciation and amortization	147	53
Stock-based compensation expense	223	165
Loss on sale and disposal of property and equipment	3	-
Changes in operating assets and liabilities:		
Accounts receivable	(30)	7
Prepaid expenses and other assets	(44)	(248)
Inventories	16	-
Accounts payable, accrued liabilities and other liabilities	(413)	202
Deferred revenue	-	(173)
Net cash used in operating activities	(4,995)	(4,525)
Cash flows from investing activities:		
Purchase of property and equipment	(578)	(37)
Net cash used in investing activities	(578)	(37)
Cash flows from financing activities:		
Repayment of capital lease obligations	(7)	-
Issuance costs related to 2014 private placement	-	(93)
Repayment of short-term debt	-	(1,069)
Proceeds from issuance of common stock from exercise of stock options	5	-
Net cash used in financing activities	(2)	(1,162)
Net decrease in cash and cash equivalents	(5,575)	(5,724)
Cash and cash equivalents, beginning of period	18,642	22,965
Cash and cash equivalents, end of period	$ 13,067	$ 17,241
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	(3)	-

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 10, 2015, the Company distributed OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics") (see Note 2). Since August 10, 2015, the Company has distributed all but a nominal number of OVA1 tests through Vermillion's wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, Inc. ("ASPiRA LABS"), which opened in June 2014. The Company also plans to offer 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. The Company plans for ASPiRA IVD to be a specialized laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. The Company's goal is to build ASPiRA IVD around a core of laboratory expertise and a United States Food and Drug Administration ("FDA")-compliant quality system, with an emphasis on delivering 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 $375,485,000 at March 31, 2016. The Company expects to incur a net loss and negative cash flows from operations in 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

Revenue Recognition

The Company has adopted ASC 954-605, Health Care Entities—Revenue Recognition as revenue from laboratory services has become more significant to the Company. The Company's 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.

Revenue recognized when cash is received and on an accrual basis for the three months ended March 31, 2016 and 2015 was as follows:

(in thousands)	Three Months Ended March 31, 2016	2015
Revenue recognized from Quest Diagnostics	$ -	$ 609
Revenue recognized when cash is received	341	26
Revenue recognized on an accrual basis	164	-
Total	$ 505	$ 635

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

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 up to three 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. This line of credit was collateralized by certain of the Company's intellectual property assets. 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 on March 11, 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.

On March 11, 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 10, 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.

On June 17, 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 are to be 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 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 depending on job attainment as compared to the required amount.

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, including its principal facility and CLIA laboratory located in Austin, Texas. As of March 31, 2016 there were two Austin, Texas leases which included an aggregate annual base rent of $115,000 and annual estimated common area charges, taxes and insurance of $58,000. The lease which includes the CLIA laboratory expires on May 31, 2017 and an additional lease is month to month and requires 90 days' notice to cancel.

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.

Rental expense under operating leases for the three months ended March 31, 2016 and 2015 totaled $51,000 and $42,000, respectively.

Capital Lease

In April 2015, the Company agreed to lease two laboratory instruments for a total initial payment of $250,000 and ongoing payments of approximately $7,000 per month for 36 months after delivery. The agreement also requires minimum annual purchases of reagents from the manufacturer of the equipment. As of March 31, 2016, one instrument has been delivered and placed into service.

The accumulated amortization of assets under capital lease obligations was $58,000 and the net book value of assets under capital lease obligations was $174,000 as of March 31, 2016. There were no assets under capital lease obligations as of March 31, 2015.

Non-cancelable Royalty Obligations

The Company is a party to an amended research collaboration agreement with The Johns Hopkins University School of Medicine ("JHU") under which the Company licenses certain of its intellectual property. Under the terms of the amended research collaboration agreement, Vermillion is required to pay the greater of 4% royalties on net sales of diagnostic tests using the assigned patents or annual minimum royalties of $57,500. Royalty expense for the three

months ended March 31, 2016 and 2015 totalled $20,000 and $25,000, 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 three months ended March 31, 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 will vest 50% on June 1, 2016 and 25% on each of September 1, 2016 and December 1, 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 vest fully on February 5, 2017. In addition, during the three months ended March 31, 2016 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 allocation of employee stock-based compensation expense by functional area for the three months ended March 31, 2016 and 2015 was as follows:

	Three Months Ended March 31,	
(in thousands)	2016	2015
Cost of revenue	$ 24	$ 9
Research and development	31	31
Sales and marketing	42	37
General and administrative	105	88
Total	$ 202	$ 165

5. LOSS PER SHARE

The Company calculates basic loss per share using the weighted average number of common shares 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 common stock outstanding and excludes the effects of 8,709,504 and 7,040,587 potential shares of common stock as of March 31, 2016 and 2015, respectively, that are anti-dilutive. Potential shares of common stock include incremental shares of 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 and was paid $375 per hour, with a minimum payment of $51,750 for the period up to the expiration of the agreement on March 31, 2016. As of March 31, 2016, the Company had paid Mr. Schreiber $13,000, and an additional $39,000 was payable to him under such 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:

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projections or expectations regarding our future revenue, cost of revenue, operating expenses, cash flow, results of operations and financial condition;

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our plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders;

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our planned business strategy and the anticipated timing of the implementation thereof;

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expected timing of the implementation of our strategy;

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plans with respect to our market expansion and growth, including plans to market Overa outside the

United States;

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plans to develop new algorithms and molecular diagnostic tests;

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plans to establish our own payer coverage for OVA1 and Overa;

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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;

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plans to leverage infrastructure and enhance our pipeline of future technologies by fostering relationships with in vitro diagnostic ("IVD") companies;

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plans with respect to ASPiRA IVD, Inc. ("ASPiRA IVD");

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anticipated efficacy of our products, product development activities and product innovations;

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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;

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plans to expand our ovarian cancer franchise beyond OVA1, including with respect to Overa and OvaX;

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plans regarding the commercialization of Overa;

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plans to develop and perform laboratory development tests (“LDTs”);

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plans with respect to product development

grants and the Cancer Prevention and Research Institute of Texas ("CPRIT") grant to help fund the Company's pelvic mass registry;

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expectations regarding existing and future collaborations and partnerships;

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anticipated liquidity and capital requirements;

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anticipated future losses and our ability to continue as a going concern;

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plans with respect to our financing arrangement with the State of Connecticut Department of Economic and Community Development (the "DECD");

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expected expenditures;

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our ability to use our net operating loss carryforwards; and

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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 this Quarterly Report on Form 10-Q, that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including our ability to 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 2016.

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 and plan to establish our own payer coverage for OVA1 and 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. On October 26, 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. On February 11, 2016, we adopted a plan to streamline our organization. We have 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 first 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 began creating a new service within the ASPiRA channel strategy, "an ASPiRA IVD Services Program". In April 2016, we formed ASPiRA IVD with plans to offer IVD trial services to third-party customers. We plan for ASPiRA IVD to be a specialized laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. Our goal is to build ASPiRA IVD around a core of laboratory expertise and a FDA-compliant quality system, with an emphasis on delivering accurate and reliable results to its third-party customers suitable for FDA submission. ASPiRA IVD has applied for a CLIA laboratory license and intends to commence operations in the third 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;

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- 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 CPRIT for $7,500,000, to help fund the Company's new multi-site pelvic mass registry. The grant would assist the Company in creating a first-in-kind clinical registry of patients undergoing evaluation, diagnosis, treatment and follow-up for pelvic masses that may lead to gynecologic malignancy. Receipt of the grant award is subject to execution of a grant contract on terms acceptable to both Vermillion and CPRIT which may include such terms as payment of future product royalties to CPRIT by Vermillion. Negotiations with CPRIT are ongoing.

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,” to be published in the peer-reviewed journal Current Medical Research & Opinion, is now available online as a pre-print (10.1080/03007995.2016.1176014).

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.

On May 13, 2016, we entered into our first international distribution agreement for Overa. Bio-Medical Science Co., Ltd. will market and distribute Overa on an exclusive basis in South Korea.

Critical Accounting Policies and Estimates

Revenue Recognition

We have adopted ASC 954-605, Health Care Entities—Revenue Recognition as revenue from laboratory services has become more significant to us. Our revenue is generated by performing diagnostic services using our OVA1 test, and the service is completed upon the delivery of test results to the prescribing physician. We recognize

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 us that commit them to pay any portion of the cost of the tests in the event that their insurance declines to reimburse us. 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 we will ultimately realize require significant judgment by management. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and we 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. We pursue 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 our services, revenue is recognized when cash is received.

There have been no other material changes to our critical accounting policies and estimates as disclosed in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Results of Operations - Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015

The selected summary financial and operating data of the Company for the three months ended March 31, 2016 and 2015 were as follows:

(dollars in thousands)	Three Months Ended March 31, 2016	2015	Increase (Decrease) Amount	%
Revenue:				
Product	$ 505	$ 635	$ (130)	(20)
License	-	316	(316)	(100)
Total revenue	505	951	(446)	(47)
Cost of revenue:				
Product	528	491	37	8
Total cost of revenue	528	491	37	8
Gross profit	(23)	460	(483)	(105)
Operating expenses:				
Research and development	934	1,105	(171)	(15)
Sales and marketing	2,280	2,217	63	3
General and administrative	1,659	1,400	259	19
Total operating expenses	4,873	4,722	151	3
Loss from operations	(4,896)	(4,262)	(634)	15
Interest income	3	9	(6)	(67)
Other expense, net	(4)	116	(120)	(103)
Net loss	(4,897)	(4,137)	(760)	18

Product Revenue. Product revenue was $505,000 for the three months ended March 31, 2016 compared to $635,000 for the same period in 2015. However, product revenue for the three months ended March 31, 2015 included the one-time recognition of $163,000 in deferred product revenue upon the signing of our new agreement with Quest Diagnostics on March 11, 2015.

The number of OVA1 tests performed decreased 40% to approximately 2,265 OVA1 tests during the three months ended March 31, 2016 compared to approximately 3,783 OVA1 tests for the same period in 2015. The volume during the three months ended March 31, 2015 included 3,567 OVA1 tests performed by Quest Diagnostics. All tests for the three months ended March 31, 2016 were performed by ASPiRA LABS. The decrease is attributed to volume loss incurred in the transition of testing from Quest Diagnostics to ASPiRA LABS in August 2015.

We expect product revenue to increase modestly in the second quarter of 2016 due to improved cash collections 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 and thus recognition of revenue lags behind the performance of an OVA1 test.

License Revenue. There was no license revenue recognized for the three months ended March 31, 2016 compared to $316,000 for the same period in 2015. We do not expect to recognize any license revenue in future quarters.

Cost of Revenue. Cost of product revenue was $528,000 for the three months ended March 31, 2016 compared to $491,000 for the same period in 2015. The $37,000, or 8%, increase is related to costs associated with processing the full volume of OVA1 tests at ASPiRA LABS after the cutover of volume from Quest Diagnostics to ASPiRA LABS on August 10, 2015. We expect the cost of revenue to remain consistent in the second 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 March 31, 2016 decreased $171,000, or 15%, compared to the same period in 2015. This decrease was primarily due to a one-time product development consulting project in 2015 not being repeated in 2016. We expect research and development expense to remain consistent in the second quarter of 2016 and until launch of our new clinical registry study.

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 increased $63,000, or 3%, for the three months ended March 31, 2016 compared to the same period in 2015. The increase was due to severance costs incurred in our February 2016 restructuring. We expect sales and marketing expenses to decrease in future quarters as a result of the restructuring effort.

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 $259,000, or 19%, for the three months ended March 31, 2016 compared to the same period in 2015. The increase was primarily due to a $140,000 investment in our new IVD trial services laboratory and increased consulting fees in 2016 compared to the same period in 2015.

Other Income (Expense), Net. Other expense was $4,000 for the three months ended March 31, 2016 compared to other income of $116,000 in the same period in 2015. Other income for the three months ended March 31, 2015 related to recognition of one-time items related to the March 11, 2015 agreement with Quest Diagnostics.

Liquidity and Capital Resources

We plan to continue to expend resources in the selling and marketing of OVA1 and Overa and developing additional diagnostic tests and service capabilities.

We have incurred significant net losses and negative cash flows from operations since inception. At March 31, 2016, we had an accumulated deficit of $375,485,000 and stockholders' equity of $12,877,000. As of March 31, 2016, we had $13,067,000 of cash and cash equivalents and $2,940,000 of current liabilities. Working capital was $10,991,000 and $16,015,000 at March 31, 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 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 $4,995,000 for the three months ended March 31, 2016 resulting primarily from the net loss reported of $4,897,000 and changes in accounts payable, accrued and other liabilities of

$413,000 partially offset by stock compensation expense of $223,000 and depreciation and amortization of $147,000.

Net cash used in operating activities was $4,525,000 for the three months ended March 31, 2015 resulting primarily from the net loss reported of $4,137,000 and non-cash license revenue of $316,000.

Net cash used in investing activities was $578,000 and $37,000 for the three months ended March 31, 2016 and 2015, respectively. This increase resulted primarily from purchases of property and equipment.

Net cash used in financing activities of $2,000 for the three months ended March 31, 2016 resulted from repayments of capital lease obligations which were partially offset by proceeds received from the exercise of stock options. Net cash used in financing activities for the three months ended March 31, 2015 resulted from the repayment of short-term debt of $1,069,000 and offering expenses incurred of $93,000.

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

We have significant net operating loss ("NOL") carryforwards as of March 31, 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.

Off-Balance Sheet Arrangements

As of March 31, 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 March 31, 2016. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of March 31, 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 March 31, 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 except as set forth below. The risks and uncertainties described below and in our 2015 Annual Report are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.

Additional Risk Factors

We are adding the following to the “Risks Related to Our Business” contained in our 2015 Annual Report:

Risks Related to our planned ASPiRA IVD Business

ASPiRA IVD is a new business venture with no operating history and may subject us to additional risks.

To date, we have no operating results with respect to providing IVD trial services to third parties through ASPiRA IVD, and, therefore, we do not have an operating history upon which you can evaluate this new line of business or its prospects. Cash in-flows from our new IVD trial services business may not meet expectations, and ASPiRA IVD’s prospects must be considered in light of the risks and uncertainties inherent in entering into a new line of business, including:

- the potential diversion of management’s attention and other resources away from our existing business;

- our relative inexperience with respect to offering IVD trial services;
- external factors, such as compliance with regulations, competitive alternatives and shifting market preferences;
- the need for additional capital and other resources to expand our IVD trial services business; and
- its impact on our system of internal controls.

Failure to successfully manage these risks in the development and implementation of ASPiRA IVD's new IVD trial services business could have an adverse effect on our business, financial condition and results of operations.

The success of ASPiRA IVD depends on our ability to generate and maintain new business awards and contracts, and if we fail to do so, it could adversely affect our business, financial condition and results of operations.

The success of ASPiRA IVD depends on our ability to generate new business awards and new customers and contracts for clinical development services and other services. The time between when a study is awarded and when it goes to contract can be several months, and prior to a new business award going to contract, our potential customers will be able to cancel the award without notice. We expect that, once an award goes to contract, the majority of our customers will be able to terminate the contract with 30 days' notice. Our IVD contracts may be delayed or terminated by our customers or reduced in scope for a variety of reasons beyond our control, including the following:

- decisions to forego or terminate a particular trial;
- budgetary limits or changing priorities;
- actions by regulatory authorities;
- production problems resulting in shortages of the drug or device being tested;
- failure of products being tested to satisfy safety requirements or efficacy criteria;
- unexpected or undesired clinical results for products;
- insufficient patient enrollment in a trial;
- insufficient principal investigatory recruitment;
- shift of business to a competitor or internal resources; or
- product withdrawal following market launch.

As a result, we expect that contract terminations, delays and modifications will be a regular part of ASPiRA IVD's business. In the event of termination, ASPiRA IVD's contracts will provide for fees for winding down the project, which include both fees incurred and actual and non-cancellable expenditures, and may also include a fee to cover a percentage of the remaining professional fees on the project. These fees may not be sufficient for us to maintain our margins, and termination may result in lower resource utilization rates and therefore lower operating margins. Cancellation of a clinical trial may also result in the unwillingness or inability of our customer to satisfy certain associated accounts receivable. Additionally, a change in the timing of a new business award could affect the period over which we recognize revenue and reduce our revenue in any one quarter. If ASPiRA IVD is unable to generate new business awards on a timely basis and subsequently enter into and maintain contracts for such awards, our business, financial condition and results of operations could be adversely affected.

Operating results for ASPiRA IVD may fluctuate significantly between fiscal quarters, which may adversely affect the market price of our stock.

Operating results for ASPiRA IVD may fluctuate significantly from quarter to quarter and may be influenced by a variety of factors, such as:

- timing of contract amendments for changes in scope that could affect the value of a contract and potentially impact the amount of net new business awards and net service revenues from quarter to quarter;
- commencement, completion, execution, postponement or termination of large contracts;
- contract terms for the recognition of revenue milestones;
- progress of ongoing contracts and retention of customers;
- changes in the mix of services we are contracted to perform; and
- potential customer disputes, penalties, or other issues that may impact the revenue we are able to recognize or the collectability of our related accounts receivable.

ASPiRA IVD's operating results for any particular quarter will not necessarily be a meaningful indicator of its future results. The resulting fluctuations in the Company's quarterly operating results could negatively affect the market price and liquidity of shares of our common stock.

If we underprice our IVD contracts, overrun our IVD cost estimates or fail to receive approval for or experience delays in documentation of IVD change orders, it could adversely affect our business, financial condition and results of operations.

We plan to price our IVD contracts based on assumptions regarding the scope of work required and cost to complete the work. We will bear the financial risk if we initially underprice our contracts or otherwise overrun our cost estimates, which could adversely affect ASPiRA IVD's cash flows and financial performance. In addition, we anticipate that contracts with ASPiRA IVD's customers will be subject to change orders, which may occur when the scope of work we perform needs to be modified from that originally contemplated in our customer contracts. This can occur, for example, when there is a change in a key study assumption or parameter or a significant change in timing. We may be unable to successfully negotiate changes in scope or change orders on a timely basis or at all, which may require us to incur cost outlays ahead of the receipt of any additional revenue. In addition, under generally accepted accounting principles in the United States of America we will not be able to recognize additional revenue anticipated from change orders until appropriate documentation is received by us from the customer authorizing the change. However, if we incur additional expense in anticipation of receipt of that documentation, we will need to recognize the expense as incurred. Any of the foregoing could adversely affect our business, financial condition and results of operations.

The operation of ASPiRA IVD will depend on the effectiveness and availability of our information systems, including the information systems we use to provide services to our customers and to store employee data, and failures of these systems, including in connection with cyber-attacks, may materially limit our operations or have an adverse effect on our reputation.

The information systems we intend to use for our IVD trial business are comprised of systems we have purchased or developed, legacy information systems from Vermillion and, increasingly, web-enabled and other integrated information systems. In using these information systems, we may rely on third-party vendors to provide hosting services, where our infrastructure is dependent upon the reliability of their underlying platforms, facilities and communications systems. We also plan to utilize integrated information systems that we provide customers access to or install for our customers in conjunction with our delivery of services.

As the breadth and complexity of ASPiRA IVD's information systems grows, we will increasingly be exposed to the risks inherent in maintaining the stability of our legacy systems due to prior customization, attrition of employees or vendors involved in their development, and obsolescence of the underlying technology as well as risks from the increasing number and scope of external data breaches on companies generally. Because certain customers and clinical trials may be dependent upon these legacy systems, we will also face an increased level of embedded risk in maintaining the legacy systems and limited options to mitigate such risk. We are also exposed to risks associated with the availability of all of our information systems, including:

- disruption, impairment or failure of data centers, telecommunications facilities or other key infrastructure platforms, including those maintained by third-party vendors;
- security breaches of, cyber-attacks on and other failures or malfunctions in our internal systems, including our employee data and communications, critical application systems and their associated hardware; and
- excessive costs, excessive delays and other deficiencies in systems development and deployment.

The materialization of any of these risks may impede the processing of data, the delivery of databases and services, and the day-to-day management of our IVD trial business and could result in the corruption, loss or unauthorized disclosure of proprietary, confidential or other data. While we have disaster recovery plans in place in line with applicable regulations and industry standards, they might not adequately protect us in the event of a system failure. Despite any precautions we take, damage from fire, floods, hurricanes, the outbreak or escalation of war, acts of terrorism, power loss, telecommunications failures, computer viruses, break-ins and similar events at our various computer facilities or those of our third-party vendors could result in interruptions in the flow of data to us

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and from us to our customers. Corruption or loss of data may result in the need to repeat a trial at no cost to the customer, but at significant cost to us, the termination of a contract or damage to our reputation. As our business continues its efforts to expand globally, these types of risks may be further increased by instability in the geopolitical climate of certain regions, underdeveloped and less stable utilities and communications infrastructure, and other local and regional factors. Additionally, significant delays in system enhancements or inadequate performance of new or upgraded systems could damage our reputation and harm our business. Although we carry property and business interruption insurance which we believe is customary for our industry, our coverage might not be adequate to compensate us for all losses that may occur.

Unauthorized disclosure of sensitive or confidential data, whether through systems failure or employee negligence, cyber-attacks, fraud or misappropriation, could damage our reputation and cause us to lose customers and, to the extent any such unauthorized disclosure compromises the privacy and security of individually identifiable health information, could also cause us to face sanctions and fines under the Federal Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act of 2009. Similarly, we have been and expect that we will continue to be subject to attempts to gain unauthorized access to or through our information systems or those we internally or externally develop for our customers, including a cyber-attack by computer programmers and hackers who may develop and deploy viruses, worms or other malicious software programs, process breakdowns, denial-of-service attacks, malicious social engineering or other malicious activities, or any combination of the foregoing. In addition, we may be susceptible to physical or computer-based attacks by terrorists or hackers due to ASPiRA IVD’s role in the contract research organization industry. These concerns about security are increased when information is transmitted over the Internet. Threats include cyber-attacks such as computer viruses, worms or other destructive or disruptive software, and any of these could result in a degradation or disruption of our services or damage to our properties, equipment and data. They could also compromise data security. If such attacks are not detected immediately, their effect could be compounded. Successful attacks could result in negative publicity, significant remediation and recovery costs, legal liability and damage to our reputation and could have an adverse effect on our business, financial condition and results of operations.

If ASPiRA IVD fails to perform its services in accordance with contractual requirements, regulatory standards and ethical considerations, we could be subject to significant costs or liability and our business or reputation could be harmed.

We anticipate that ASPiRA IVD will contract with biopharmaceutical companies to perform a wide range of services to assist them in bringing new drugs to market. Our IVD trial services will include monitoring clinical trials, data and laboratory analysis, patient recruitment and other related services. Such services are complex and subject to contractual requirements, regulatory standards and ethical considerations. For example, ASPiRA IVD will be required to adhere to applicable regulatory requirements such as the FDA’s Quality System Regulations, CLIA, and current Good Clinical Practices, which govern, among other things, the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. If ASPiRA IVD fails to perform its services in accordance with these requirements, regulatory authorities may take action against us or our customers. Such actions may include sanctions (e.g., injunctions or the failure of such regulatory authorities to grant marketing approval of products), imposition of clinical holds or delays, suspension or withdrawal of approvals, rejection of data collected in studies conducted by ASPiRA IVD, license revocation, product seizures or recalls, operational restrictions, civil or criminal penalties or prosecutions, damages or fines. Additionally, there is a risk that actions by regulatory authorities, if they result in significant inspectional observations or other measures, could harm our reputation and cause customers not to award ASPiRA IVD future contracts or to cancel existing contracts. Any such action could have an adverse effect on our business, financial condition and 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				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated January 22, 2010	8-K	000-31617	3.1	January 25, 2010	
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation, effective June 19, 2014	10-Q	001-34810	3.2	August 14, 2014	
3.3	Fifth Amended and Restated Bylaws of Vermillion, Inc., effective June 19, 2014	10-Q	001-34810	3.3	August 14, 2014	
10.1	Assistance Agreement by and between the State of Connecticut, acting by and through the Department of Economic and Community Development and Vermillion, Inc., effective March 22, 2016					√
10.2	Promissory Note by Vermillion, Inc. in favor of the State of Connecticut, acting by					√

	and through the Department of Economic and Community Development, effective March 14, 2016	
10.3	Patent Security Agreement by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective March 22, 2016	√
10.4	Security Agreement by Vermillion, Inc. in favor of the State of Connecticut, acting by and through the Department of Economic and Community Development, effective March 22, 2016	√
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.	(1)

	Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
101	Interactive Data Files	√

(1) Furnished herewith

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vermillion, Inc.

Date: May 16, 2016 /s/ Valerie B. Palmieri
Valerie B. Palmieri

President and Chief Executive Officer

(Principal Executive Officer)

Date: May 16, 2016 /s/ Eric J. Schoen
Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)