VERMILLION, INC.
Form 10-Q
November 12, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2015

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 (State or Other Jurisdiction of Incorporation or Organization)	33-0595156 (I.R.S. Employer Identification No.)
12117 Bee Caves Road, Building Three, Suite 100, Austin, Texas (Address of Principal Executive Offices)	78738 (Zip Code)

(512) 519-0400

(Registrant’s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

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

As of October 31, 2015, the registrant had 52,009,716 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.

Consolidated Balance Sheets

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

(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 23,974	$ 22,965
Accounts receivable	68	167
Prepaid expenses and other current assets	411	526
Inventories	81	-
Total current assets	24,534	23,658
Property and equipment, net	765	508
Other assets	90	8
Total assets	$ 25,389	$ 24,174
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 803	$ 1,123
Accrued liabilities	2,245	2,201
Short-term debt	-	1,106
Deferred revenue	-	489
Other current liabilities	154	-
Total current liabilities	3,202	4,919
Lease obligation - long term	71	-
Total liabilities	3,273	4,919
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued		

and outstanding at September 30, 2015 and December 31, 2014	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized at September 30, 2015 and December 31, 2014; 52,009,716 and 43,115,790 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	52	43
Additional paid-in capital	387,669	370,685
Accumulated deficit	(365,605)	(351,473)
Total stockholders' equity	22,116	19,255
Total liabilities and stockholders' equity	$ 25,389	$ 24,174

See accompanying notes to the unaudited consolidated financial statements.

Vermillion, Inc.

Consolidated Statements of Operations

(Amounts in Thousands, Except Share and Per Share Amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Product	$ 330	$ 209	$ 1,500	$ 611
License	-	114	316	341
Total revenue	330	323	1,816	952
Cost of revenue:				
Product	757	606	1,822	749
Total cost of revenue	757	606	1,822	749
Gross profit (loss)	(427)	(283)	(6)	203
Operating expenses:				
Research and development(1)	874	1,263	2,898	3,473
Sales and marketing(2)	2,462	2,762	7,238	7,632
General and administrative(3)	1,380	1,281	4,111	4,240
Total operating expenses	4,716	5,306	14,247	15,345
Loss from operations	(5,143)	(5,589)	(14,253)	(15,142)
Interest income	11	8	26	34
Other income (expense), net	(14)	(10)	95	(25)
Net loss	$ (5,146)	$ (5,591)	$ (14,132)	$ (15,133)
Net loss per share - basic and diluted	$ (0.10)	$ (0.16)	$ (0.31)	$ (0.42)
Weighted average common shares used to compute basic and diluted net loss per common share	50,297,031	35,913,580	45,483,889	35,865,089
Non-cash stock-based compensation expense included in operating expenses:				
(1) Research and development	$ 44	$ 32	$ 107	$ 103
(2) Sales and marketing	81	164	154	233
(3) General and administrative	420	159	648	518

See accompanying notes to the unaudited consolidated financial statements.

Vermillion, Inc.

Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (14,132)	$ (15,133)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt	(37)	-
Non-cash license revenue	(316)	(341)
Depreciation and amortization	197	93
Stock-based compensation expense	908	832
Warrants issued for services	-	22
Changes in operating assets and liabilities:		
Accounts receivable	99	194
Prepaid expenses and other assets	33	(564)
Inventories	(81)	-
Accounts payable, accrued liabilities and other liabilities	(278)	1,398
Deferred revenue	(173)	901
Net cash used in operating activities	(13,780)	(12,598)
Cash flows from investing activities:		
Purchase of property and equipment	(222)	(232)
Net cash used in investing activities	(222)	(232)
Cash flows from financing activities:		
Repayment of capital lease obligations	(5)	-
Repurchase of common stock	(1,291)	-
Issuance costs related to 2014 private placement	(122)	-
Proceeds from sale of common stock, net of issuance costs	17,496	-
Repayment of short-term debt	(1,069)	-
Proceeds from issuance of common stock from exercise of stock options	2	88
Net cash provided by financing activities	15,011	88
Net increase (decrease) in cash and cash equivalents	1,009	(12,742)
Cash and cash equivalents, beginning of period	22,965	29,504
Cash and cash equivalents, end of period	$ 23,974	$ 16,762
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	2	-
Supplemental disclosure of noncash investing and financing activities:		
Equipment acquired through capital lease agreements	107	-

Changes in other current liabilities related to equipment	125	-

See accompanying notes to the unaudited consolidated financial statements.

Vermillion, Inc.

Notes to 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. In March 2010, the Company commercially launched OVA1™ risk of malignancy test for pelvic mass disease ("OVA1"). The Company distributed OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics") (see Note 2) through August 10, 2015. Since August 10, 2015, the Company has distributed all but a nominal number of OVA1 tests distributed through Quest Diagnostics through its wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, Inc. ("ASPiRA LABS"), which opened in June 2014.

Liquidity

The Company believes that its working capital position as of the date of the filing of this Quarterly Report on Form 10-Q will be sufficient to meet the Company's working capital needs for at least the next 12 months.

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 consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim unaudited consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. The consolidated balance sheet at December 31, 2014 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 consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2014, included in Vermillion's Annual Report on Form 10-K which was filed with the Securities and Exchange Commission on March 31, 2015.

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.

Certain reclassifications of prior year amounts have been made to conform to current year presentation.

Significant Accounting and Reporting Policies

The Company has made no significant changes in its critical accounting policies and estimates from those disclosed in Vermillion's Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

In July 2015, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2015-11 Inventory (Topic 330): Simplifying the Measurement of Inventory ("ASU No. 2015-11"). ASU 2015-11 changes the measurement of inventory from the lower of cost or market to the lower of cost and net realizable value. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2016. The Company does not anticipate a material impact on its consolidated financial statements from the adoption of this ASU.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU No. 2014-09"). ASU 2014-09 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 currently evaluating the impact of this ASU on its consolidated financial statements and related disclosures.

2. AGREEMENTS WITH QUEST DIAGNOSTICS INCORPORATED

In July 2005, the Company entered into a Strategic Alliance Agreement (as amended, the "Strategic Alliance Agreement") with Quest Diagnostics to develop and commercialize diagnostic tests, including OVA1, 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 three months ended March 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

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 near Austin, Texas. The Austin, Texas leases include an aggregate annual base rent of $130,000 and annual estimated common area charges, taxes and insurance of $62,000 and expire at various times prior to May 31, 2016.

On October 7, 2015, the Company entered a lease agreement for a facility in Trumbull, Connecticut. The lease includes initial payments for the buildout of leasehold improvements to the office space, which are estimated to be approximately $438,000. The term of the lease is five years beginning after the initial date of occupancy and a rent abatement period of five months. The lease includes an aggregate annual base rent of $32,000 in addition to common area charges, taxes and insurance.

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 September 30, 2015, one instrument has been delivered and placed into service.

4. STOCKHOLDERS' EQUITY

On July 17, 2015 the Company completed the sale of 9,602,500 shares of Vermillion common stock, including 1,252,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in an underwritten public offering at a price of $1.96 per share. The Company received net proceeds from the offering of $17,496,000 after deducting underwriting discounts and offering expenses.

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 under the 2010 Plan, subject to adjustment as provided in the 2010 Plan.

Employee Stock-Based Compensation

During the nine months ended September 30, 2015, the Company granted to the Company's President and Chief Executive Officer options to purchase 400,000 shares of Vermillion common stock with an exercise price of $1.95 per share. These stock options vest in 48 equal monthly instalments from the date of the grant. During the nine months ended September 30, 2015, the Company also granted to certain Vermillion officers options to purchase 275,000 shares of Vermillion common stock with an exercise price of $2.08 and granted to certain Vermillion employees options to purchase 45,000 shares of Vermillion common stock with an exercise price of $1.77. These stock options vest 25% on the first anniversary of the grant date, and the remaining stock options vest ratably over the following 36-month period. During the nine months ended September 30, 2015, the Company granted to a Vermillion officer options to purchase 150,000 shares of Vermillion common stock with an exercise price of $1.74 per share. 25% of these stock options vest on the first anniversary of the grant date, and the remaining stock options vest ratably over the following 36-month period. The Company also granted to officers and employees of the Company options to purchase 317,000 shares of Vermillion common stock with an exercise price of $2.03 per share. These stock options vest 25% on each of the four anniversaries of the grant date. The Company also granted to employees of the Company options to purchase 37,500 shares of Vermillion common stock with an exercise price of $2.05 per share. These stock options vest 25% on each of the four anniversaries of the grant date. In addition, the Company granted certain officers options to purchase 400,000 shares of Vermillion common stock with an exercise price of $2.03 per share with performance-based vesting based on certain metrics through December 31, 2016.

During the nine months ended September 30, 2015, the Company awarded 181,369 shares of restricted stock under the 2010 Plan having a fair value of approximately $370,000 to Vermillion's Board of Directors as stock-based payment for services rendered in 2015. 50% of these shares of restricted stock vested on July 13, 2015. 25% of these shares of restricted stock vested on September 1, 2015, and the remaining 25% will vest on December 1, 2015.

During the nine months ended September 30, 2015, the Company awarded certain consultants of the Company options to purchase 50,000 shares of Vermillion common stock with an exercise price of $2.05 per share. These stock options vest in 24 equal monthly instalments from the date the consultant first provided services to the Company.

The allocation of employee stock-based compensation expense by functional area for the three and nine months ended September 30, 2015 and 2014 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2015	2014	2015	2014
Research and development	$ 44	$ 32	$ 107	$ 103
Sales and marketing	81	164	154	233
General and administrative	417	159	645	483
Total	$ 542	$ 355	$ 906	$ 819

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 7,972,985 and 2,563,106 potential shares of common stock as of September 30, 2015 and 2014, respectively, that are anti-dilutive. Potential shares of common stock include incremental shares of common stock issuable upon the exercise of outstanding warrants and stock options.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward Looking Statements

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

These statements involve a number of risks and uncertainties. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions to identify such forward-looking statements. Readers are cautioned that these forward-looking statements speak only as of the date on which this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission ("SEC"), and, except as required by law, Vermillion, Inc. ("Vermillion" and together with its subsidiaries, the "Company," "we," "our," or "us") does not assume any obligation to update, amend or clarify them to reflect events, new information or circumstances occurring after such date.

Examples of forward-looking statements regarding our business include the following:

- projections or expectations regarding our future revenue, cost of revenue, operating expenses, 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;
- expected timing of the implementation of our strategy;
- plans to establish our own payer coverage for OVA1;
- intentions to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and other issues in the fields of oncology and women's health;
- plans with respect to ASPiRA LABS, Inc. ("ASPiRA LABS");
- plans with respect to Overa and OvaX;
- plans to develop and perform LDTs;
- expectations regarding existing and future collaborations and partnerships;
- expectations regarding pending regulatory submissions;
- anticipated liquidity and capital requirements;
- expected expenditures; and
- our ability to use our net operating loss carryforwards;

Forward-looking statements are subject to significant risks and uncertainties, including those discussed in Part I, Item 1A "Risk Factors" of 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 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

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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; and 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").

Overview

Our Company

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 pelvic mass disease.

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 will be 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 is expected to span the remainder of 2015, 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 new heads of sales and customer experience, managed markets, marketing and operations, a chief information officer, a chief medical officer and 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 and plan to establish our own payer coverage for OVA1 and launch a second-generation OVA1 test, trademarked Overa (predicated on receipt of clearance from the FDA). 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 and other diagnostics, but also clinical risk factors 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 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 clinical research institutions.

Our lead 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 development and validation work on 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 on March 6, 2015, with the goal of commencing the marketing and sale of the panel in the fourth quarter of 2015. We received a request for additional information about this

submission from the FDA, to which we responded by submitting a formal response to the FDA. On September 8, 2015, the FDA sent a second request for additional information. As of the date of the filing of this Quarterly Report on Form 10-Q, we are in the process of preparing our response to the FDA's second request. While our goal remains to commence the marketing and sale of Overa in the fourth quarter of 2015, this timing may extend into the first quarter of 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 near Austin, Texas, which specializes in applying biomarker-based technologies to address critical needs in the management of gynecologic cancers and specifically pelvic mass disease. ASPiRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based diagnostic algorithm to inform 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. 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 ("CMS") issued a provider number to ASPiRA LABS on March 5, 2015.

We are focused on the execution of four core strategic business drivers in ovarian cancer diagnostics 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 seeking FDA clearance of Overa, a potentially better performing biomarker panel, while migrating OVA1 to a global testing platform, thus potentially allowing for better domestic market penetration and international expansion;
- Building an expanded patient base by launching a next generation multi-marker ovarian cancer test to monitor patients at risk for ovarian cancer; and
- 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 diagnosis and risk stratification of women presenting with pelvic mass disease.

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.

Our Product

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/or 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.

We terminated our Strategic Alliance Agreement with Quest Diagnostics (the “Strategic Alliance Agreement”) in August 2013. Prior to the termination of the Strategic Alliance Agreement, Quest Diagnostics had the right to be the exclusive clinical reference laboratory marketplace provider of OVA1 tests in its exclusive territory, which included the United States, Mexico, the United Kingdom and India. As part of the termination, we

agreed that Quest Diagnostics could continue to make OVA1 available to healthcare providers under legacy financial terms following the termination while negotiating in good faith towards an alternative business structure. Quest Diagnostics disputed the effectiveness of such termination.

On March 11, 2015, we reached a settlement agreement with Quest Diagnostics that terminated all disputes related to the Strategic Alliance Agreement and our prior loan agreement with Quest Diagnostics. We 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. We do not expect Quest Diagnostics to distribute additional tests in the future. 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, we will not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers.

In March 2015, we announced initial results from a cost-effectiveness analysis study which was presented in a poster at the Annual Meeting of the American College of Medical Quality in Alexandria, Virginia. The study was co-authored by Dr. Robert E. Bristow and Dr. Gareth K. Forde, clinicians at the University of California at Irvine, and Dr. John Hornberger, a leading health economist at Stanford University School of Medicine. The new study, entitled: "Cost Effectiveness Analysis of a Multivariate Index Assay compared to Modified ACOG Criteria and CA-125 in the Triage of Women with Adnexal Masses", compared the cost-effectiveness of triaging ovarian masses using OVA1 versus two important clinical benchmarks: the CA-125 biomarker and the modified ACOG (American College of Obstetricians and Gynecologists) guideline for ovarian cancer risk assessment ("mod-ACOG").

Study endpoints included treatment costs, quality-adjusted life-years ("QALYs") and incremental cost-effectiveness ratio ("ICER"). The health economic model utilized OVA1 performance data from the OVA500 prospective trial, published survival, cost and QALY parameters, and a best-practice patient management decision tree. Several important health economic and quality outcomes conclusions were reported in the study:

- Use of OVA1 resulted in fewer projected re-operations and pre-treatment CT scans versus CA 125-II or mod-ACOG,
- OVA1 was QALY-increasing and cost-effective relative to CA 125-II or mod-ACOG,
- ICERs of $12,189/QALY and $35,094/QALY were calculated for OVA1 versus CA 125-II and mod-ACOG, respectively, resulting in a "cost-effective" outcome based on the $50,000 threshold, and
- Relative to the best-practice mod-ACOG benchmark, OVA1 projected an annual increase in patient survival and QALY in excess of 1,000 years, when the surgical cohort was projected to national annual adnexal mass surgeries including about 22,000 new cases of ovarian cancer.

In April 2015, we announced the initiation of a strategic collaboration with Kaiser Permanente's Southern California Permanente Medical Group in order to enhance the diagnosis and treatment of ovarian cancer. The ultimate goal of this collaboration is to create a "best practice" for identification and "first time right" treatment of patients with ovarian cancer. The first phase of this relationship is focused on retrospective benchmarking of ovarian cancer care across the Kaiser-Permanente system in Southern California. The study will be directed from within the Women and Children's Service Line of Kaiser Permanente, Orange County. Subsequent phases are expected to include the opportunity to collaborate further in identifying a role for innovative diagnostics, such as OVA1 and Overa, in informing ovarian cancer treatment decisions to better serve patients and optimize the effectiveness of healthcare delivery.

In May 2015, we announced publication of two abstracts reporting initial positive top-line results regarding the development and validation of Overa, Vermillion's second-generation OVA1 ovarian cancer triage test. The results were presented in two posters at the 2015 American Society for Clinical Oncology annual meeting.

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The abstracts represent the first publication of data from the development of Overa. The data show significant improvement in Overa specificity compared to OVA1, while maintaining strong sensitivity (92% for OVA1 in a 2013 study). Our goal is to launch Overa by the fourth quarter of 2015, dependent on successful and timely FDA clearance.

Highlights of the abstracts are as follows:

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Validation Study† (N=493)	OVA1	Overa (MIA2G)	Variance	% Variance
Sensitivity	n.s. (not significantly different)			
Specificity	53.6%	69.1%	+15.5%*	+28.9%
Positive predictive value	31.4%	40.4%	+9.0%*	+28.7%
Negative predictive value	n.s. (not significantly different)			
False positive rate	46.4%	30.9%	(15.5%)*	(33.4%)
Overall clinical accuracy†	60.9%	73.2%	+12.3%	+20.2%

†Risk stratification performance, for analytical purposes only; OVA1/Overa are not standalone diagnostic tests

*Statistically significant difference ($p<0.001$); n.s. Difference not statistically significant ($p\geq0.05$)

In May 2015 we announced that the Company was approved for a product development grant from the Cancer Prevention and Research Institute of Texas (“CPRIT”) for $7,500,000, to help fund the Company's new multi-site pelvic mass registry. 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.

Critical Accounting Policies and Estimates

There have been no 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, 2014.

In July 2015, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2015-11 Inventory (Topic 330): Simplifying the Measurement of Inventory (“ASU No. 2015-11”). ASU 2015-11 changes the measurement of inventory from the lower of cost or market to the lower of cost and net realizable value. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2016. We do not anticipate a material impact on our consolidated financial statements from the adoption of this ASU.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASU No. 2014-09”). ASU 2014-09 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. We are currently evaluating the impact of this ASU on our consolidated financial statements and related disclosures.

Results of Operations - Three Months Ended September 30, 2015 Compared to Three Months Ended September 30, 2014

The selected summary financial and operating data of the Company for the three months ended September 30, 2015 and 2014 were as follows:

	Three Months Ended September 30,		Increase (Decrease)	
(dollars in thousands)	2015	2014	Amount	%
Revenue:				
Product	$ 330	$ 209	$ 121	58
License	-	114	(114)	-
Total revenue	330	323	7	2
Cost of revenue:				
Product	757	606	151	25
Total cost of revenue	757	606	151	25
Gross profit	(427)	(283)	(144)	51
Operating expenses:				
Research and development	874	1,263	(389)	(31)
Sales and marketing	2,462	2,762	(300)	(11)
General and administrative	1,380	1,281	99	8
Total operating expenses	4,716	5,306	(590)	(11)
Loss from operations	(5,143)	(5,589)	446	(8)
Interest income	11	8	3	38
Other expense, net	(14)	(10)	(4)	40
Net loss	(5,146)	(5,591)	445	(8)

Product Revenue. Product revenue was $330,000 for the three months ended September 30, 2015 compared to $209,000 for the same period in 2014. As a result of our March 11, 2015 agreement with Quest Diagnostics, we realize product revenue for tests performed by Quest Diagnostics after January 1, 2015 at the time the OVA1 test is performed. During the three months ended September 30, 2014, we recognized product revenue for the sale of OVA1 through Quest Diagnostics at only a $50 fixed fee per test. The number of OVA1 tests performed decreased 26% to approximately 3,183 OVA1 tests during the three months ended September 30, 2015 compared to approximately 4,325 OVA1 tests for the same period in 2014. This volume included 1,665 OVA1 tests performed by ASPiRA LABS during the three months ended September 30, 2015. Product revenue for the three months ended September 30, 2015 consisted of $190,000 from the tests performed by Quest Diagnostics and $140,000 of revenue recognized by ASPiRA LABS. We expect product revenue to decrease in the fourth quarter of 2015 due to the transition of volume from Quest Diagnostics to ASPiRA LABS. Revenue for ASPiRA LABS contractual clients is being recognized when the OVA1 test is being performed. All other ASPiRA LABS revenue is being recognized on the cash basis and thus recognition of revenue lags the performance of an OVA1 test.

License Revenue. There was no license revenue recognized for the three months ended September 30, 2015 compared to $114,000 for the same period in 2014. We do not expect to recognize any license revenue in future quarters.

Cost of Revenue. Cost of product revenue was $757,000 for the three months ended September 30, 2015 compared to $606,000 for the same period in 2014. The $151,000, or 25% 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 increase in future periods due to ongoing costs of operating ASPiRA LABS and performing higher volumes of OVA1 testing.

Research and Development Expenses. Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with our collaborators and strategic partners. Research and development expenses for the three months ended September 30, 2015 decreased $389,000, or 31% compared to the same period in 2014. This decrease was primarily due to a decrease in costs associated with our collaboration with Johns Hopkins University School of Medicine and other Overa-related development costs not being repeated in 2015. These decreases were partially offset by increased research and development headcount in 2015 compared to 2014. We expect research and development expense to increase in future periods as we continue to invest in our product pipeline, including initiation of a 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 decreased $300,000, or 11%, for the three months ended September 30, 2015 compared to the same period in 2014. The decrease was primarily due to costs associated with severance and costs related to branding ASPiRA LABS not being repeated in 2015.

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 $99,000, or 8%, for the three months ended September 30, 2015 compared to the same period in 2014. The increase was primarily due to increased headcount in 2015 compared to the same period in 2014.

Results of Operations - Nine Months Ended September 30, 2015 Compared to Nine Months Ended September 30, 2014

The selected summary financial and operating data of the Company for the nine months ended September 30, 2015 and 2014 were as follows:

	Nine Months Ended September 30,		Increase (Decrease)	
(dollars in thousands)	2015	2014	Amount	%
Revenue:				
Product	$ 1,500	$ 611	$ 889	145
License	316	341	(25)	(7)
Total revenue	1,816	952	864	91
Cost of revenue:				
Product	1,822	749	1,073	143
Total cost of revenue	1,822	749	1,073	143
Gross profit	(6)	203	(209)	(103)
Operating expenses:				
Research and development	2,898	3,473	(575)	(17)

Sales and marketing	7,238	7,632	(394)	(5)
General and administrative	4,111	4,240	(129)	(3)
Total operating expenses	14,247	15,345	(1,098)	(7)
Loss from operations	(14,253)	(15,142)	889	(6)
Interest income	26	34	(8)	(24)
Other income (expense), net	95	(25)	120	(480)
Net loss	(14,132)	(15,133)	1,001	(7)

Product Revenue. Product revenue was $1,500,000 for the nine months ended September 30, 2015 compared to $611,000 for the same period in 2014. As a result of our March 11, 2015 agreement with Quest Diagnostics, we realize product revenue for tests performed by Quest Diagnostics after January 1, 2015 at the time the OVA1 test is performed. Upon signing the agreement with Quest Diagnostics on March 11, 2015, we recognized $163,000 in deferred product revenue related to January and February 2015 which is included in product revenue for the nine months ended September 30, 2015. During the nine months ended September 30, 2014, we recognized product revenue for the sale of OVA1 through Quest Diagnostics at only a $50 fixed fee per test. The total number of OVA1 tests performed during the nine months ended September 30, 2015 decreased 10%, to 11,069 compared to 12,365 OVA1 tests for the same period in 2014. Tests performed by Quest Diagnostics during the nine months ended September 30, 2015 were 8,914 compared to 12,210 for the same period in 2014. In addition, ASPiRA LABS performed 2,155 OVA1 tests during the nine months ended September 30, 2015 compared to 155 in the comparable prior year period. We expect product revenue to decrease in the fourth quarter of 2015 due to the cutover of testing volume from Quest Diagnostics to ASPiRA LABS as of August 10, 2015. ASPiRA LABS recognizes revenue from contractual clients when the OVA1 test is performed. All other ASPiRA LABS revenue is recognized on the cash basis and thus recognition of revenue lags the performance of an OVA1 test.

License Revenue. License revenue was $316,000 for the nine months ended September 30, 2015 compared to $341,000 for the same period in 2014. We do not expect to recognize any license revenue in future quarters.

Cost of Revenue. Cost of product revenue increased $1,073,000 or 143% for the nine months ended September 30, 2015 compared to the same period in 2014. The increase is related to the ongoing costs of operating ASPiRA LABS. ASPiRA LABS opened on June 23, 2014, so only one quarter of cost was included in the comparable prior year period. We expect the cost of revenue to increase in future periods due to ongoing costs of operating ASPiRA LABS and performing higher volumes of OVA1 testing.

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 nine months ended September 30, 2015 decreased $575,000, or 17%, compared to the same period in 2014. This was primarily due to a decrease in costs associated with our collaboration with Johns Hopkins University School of Medicine since we completed the development of Overa in 2014.

Sales and Marketing Expenses. Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses decreased $394,000 or 5% for the nine months ended September 30, 2015 compared to the same period in 2014 due to slightly lower headcount in 2015.

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 were consistent for the nine months ended September 30, 2015 compared to the same period in 2014. One-time pre-opening costs for ASPiRA LABS in 2014 were not repeated in 2015 but were almost entirely offset by increased personnel costs, legal expenses and administrative costs associated with billing for tests performed by ASPiRA LABS.

Other Income (Expense), Net. Other income was $95,000 for the nine months ended September 30, 2015 compared to other expense of $25,000 in the same period in 2014. Other income for the nine months ended September 30, 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 developing additional diagnostic tests.

We have incurred significant net losses and negative cash flows from operations since inception. At September 30, 2015, we had an accumulated deficit of $365,605,000 and stockholders' equity of $22,116,000. As of September 30, 2015, we had $23,974,000 of cash and cash equivalents and $3,202,000 of current liabilities.

On July 17, 2015 we completed the sale of 9,602,500 shares of Vermillion common stock, at a price to the public of $1.96 per share, including 1,252,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in an underwritten public offering at a price of $1.96 per share. Net proceeds from the offering were approximately $17,496,000 after deducting underwriting discounts and offering expenses.

Our management believes that the Company's working capital position as of the date of the filing of this Quarterly Report on Form 10-Q will be sufficient to meet the Company's working capital needs for at least the next 12 months. However, we expect cash for OVA1 tests to be our only material, recurring source of cash for the remainder of 2015. There can be no assurance that we will achieve or sustain profitability or positive cash flow from operations. In addition, there is no assurance of our ability to generate substantial revenues and cash flows from ASPiRA LABS' operations.

In the event we seek additional capital in the future, equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants and dilution to stockholders. If we obtain additional funds through arrangements with collaborators or strategic partners, we may be required to relinquish our rights to certain technologies or products that we might otherwise seek to retain. Additional funding may not be available when needed or at terms acceptable to us.

Cash and cash equivalents as of September 30, 2015 and December 31, 2014, were $23,974,000 and $22,965,000 respectively. Working capital was $21,332,000 and $18,739,000 at September 30, 2015 and December 31, 2014 respectively.

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

Net cash used in operating activities was $12,598,000 for the nine months ended September 30, 2014 resulting primarily from the net loss reported of $15,133,000 partially offset by changes in operating assets and liabilities of $1,929,000.

Net cash used in investing activities was $222,000 and $232,000 for the nine months ended September 30, 2015 and 2014, respectively. This decrease resulted from decreased purchases of property and equipment.

Net cash provided by financing activities was $15,011,000 for the nine months ended September 30, 2015 compared to $88,000 the same period in 2014. The increase in cash provided by financing activities resulted primarily from net proceeds from the sale of common stock of $17,496,000 in July 2015, partially offset by the repurchase of common stock from Quest Diagnostics, in the amount of $1,291,000, the repayment of short-term debt of $1,069,000 to Quest Diagnostics and $122,000 of offering expenses relating to our December 2014 private placement. Net cash provided by financing activities for the nine months ended September 30, 2014 consisted of proceeds from stock option exercises.

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;

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

We have significant net operating loss ("NOL") carryforwards as of September 30, 2015 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 September 30, 2015, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Per Item 305(e) of Regulation S-K, information is not required.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

Our senior management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management, including our Chief Executive Officer and Chief Accounting Officer, performed an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2015. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of September 30, 2015, our disclosure controls and procedures were effective.

Changes in internal controls over financial reporting.

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

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Investing in our securities involves a high degree of risk. You should carefully consider the following risk factors and uncertainties together with all of the other information contained in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, including our audited consolidated financial statements and the accompanying notes. If any of the following risks materializes, our business, financial condition and results of operations could be materially adversely affected, and the value of an investment in our common stock may decline significantly. The risks and uncertainties described below 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 and results of operations.

Risks Related to Our Business

If we are unable to increase the volume of OVA1 sales, our business, results of operations and financial condition will be adversely affected.

We have experienced significant operating losses each year since our inception and we expect to incur a net loss for fiscal year 2015 and the foreseeable future. Our losses have resulted principally from costs incurred in research and development, sales and marketing, and general and administrative costs.

Historically, all of our revenues were generated from sales of OVA1 tests performed by Quest Diagnostics. Pursuant to our March 2015 agreement with Quest Diagnostics, OVA1 testing in the United States for Quest Diagnostics customers was transitioned from Quest Diagnostics to ASPiRA LABS as of August 10, 2015, with the exception of a nominal number of OVA1 tests distributed through Quest Diagnostics after that date. We do not expect that Quest Diagnostics will distribute additional tests in the future. If we are unable to increase the volume of OVA1 sales, our consolidated results of operations and financial condition would be adversely affected.

Virtually all of our revenue was derived from Quest Diagnostics during 2014, and there is no guarantee that we will be able to successfully market our test through additional channels, including ASPiRA LABS, in the future.

Virtually all of our revenue during 2014 was derived through our strategic partnership with Quest Diagnostics and was based on the number of OVA1 tests performed by Quest Diagnostics and the reimbursement rate received by Quest Diagnostics for those tests. On March 11, 2015, we entered into a new agreement with Quest Diagnostics pursuant to which, Quest Diagnostics transitioned OVA1 testing services for its customers to ASPiRA LABS as of August 10, 2015, with the exception of a nominal number of OVA1 tests distributed through Quest Diagnostics after that date. We still depend on Quest Diagnostics for blood draw and logistics for a significant portion of our specimens. There is no guarantee that Quest Diagnostics will perform as expected, or provide a sufficient volume of OVA1 test samples to support our business. Due in part to this uncertainty, we plan to offer OVA1 through additional channels in the future. However, if we are not successful in adding additional sales

channels or if we do not experience growing OVA1 test volumes or receive less reimbursement per test than expected, it could have a material adverse effect on our business, results of operations and financial condition.

Failures by third-party payers to reimburse OVA1 or changes or variances in reimbursement rates could materially and adversely affect our business, financial condition and results of operations.

Virtually all of our product revenue in 2014 was dependent on the amount Quest Diagnostics received from third-party payers for performing OVA1 tests, and our future revenues will also be dependent upon third-party reimbursement, which is now paid directly to ASPiRA LABS. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to change and particularly volatile during the early stages of commercialization. There remain questions as to what extent third-party payers, like Medicare, Medicaid and private insurance companies will provide coverage for OVA1 and for which indications. CMS is in the process of developing payment codes and reimbursement rates under Medicare for certain next-generation sequencing tests which may include certain Multianalyte Assays with Algorithmic Analyses, such as our OVA1 test. These new payment codes and rates are expected by January 1, 2016, but there is no guarantee that CMS will issue them at that time, that the codes will cover the OVA1 test or that the payment rate will be comparable to current Medicare reimbursement levels for the test. Such uncertainty could create payment uncertainty from other payers as well. The reimbursement rates for OVA1 are largely out of our control. We have had limited visibility into any specific payer-level reimbursement data for OVA1 because such data was historically provided to us by Quest Diagnostics once a year as part of the annual revenue true-up process. Quest Diagnostics has advised us that it has experienced volatility in the coverage and reimbursement of OVA1 due to contract negotiation with third-party payers and implementation requirements and that the reimbursement amounts it has received from third-party payers varies from payer to payer, and, in some cases, the variation is material. In addition, there is no guarantee that our third-party payer experience will be similar to that of Quest Diagnostics.

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

We may need to raise additional capital in the future and if we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our business plan.

We may seek to raise additional capital through the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. The availability of financing opportunities will depend, in part, on market conditions, and the outlook for our business. Any future issuance of equity securities or securities convertible into equity could result in substantial dilution to our stockholders, and the securities issued in such a financing may have rights, preferences or privileges senior to those of our common stock. If we are unable to obtain additional capital, we may not be able to continue our sales and marketing, research and development or other operations on the scope or scale of our current activity.

Our success depends, in part, on our ability to commercialize OVA1 outside the United States, and there is no assurance that we will be able to do so successfully.

In 2014, all of our product revenue was generated in the United States. In 2015, we plan to begin to actively seek laboratory customers and other distributors and partners outside the United States, so that we may begin directly or indirectly marketing and selling Overa outside the United States in 2016. We may not be able to find suitable customers or other distributors or partners outside the United States that are willing to enter into business relationships with us on terms that are advantageous to us or at all. Moreover, while we registered the CE mark and in October 2015 obtained clearance to market Overa in the European Union, we may be prohibited in the future from directly or indirectly marketing or selling Overa in the European Union or various other jurisdictions outside the United States if we are unable to maintain or obtain applicable regulatory approvals. In addition, we will need to ensure that third-party payers, including insurance companies and government payers, in jurisdictions outside the United States will pay or reimburse for Overa tests performed in those jurisdictions.

If we are able to establish operations in countries outside of the United States, we may be subject to political, economic and other conditions affecting these countries that could result in increased operating expenses and regulation.

If we are able to execute on our plan to establish a market for Overa outside the United States, there are risks inherent in conducting business internationally, including the following:

- data privacy laws that may apply to the transmission of any clients' and employees' data to the United States;
- import/export sanctions and restrictions;
- compliance with applicable anti-corruption laws;
- difficulties in managing international distributors;
- accounting, tax and legal complexities arising from international operations;
- potential difficulties in transferring funds generated overseas to the United States in a tax efficient manner; and
- political and economic instability, including recent recessionary trends.

If we are able to establish operations in countries outside of the United States, changes in foreign exchange rates may adversely affect our revenue and net income.

If we are able to successfully commercialize Overa outside the United States, we expect that revenue and expense from our foreign operations will typically be denominated in local currencies, thereby creating exposure to changes in exchange rates. Revenue and profit generated by any international operations will increase or decrease as a result of changes in foreign currency exchange rates. Adverse changes to foreign exchange rates could decrease the value of revenue we receive from our contemplated international operations and have a material adverse impact on our business, results of operations and financial condition.

If we fail to continue to develop our existing technologies, we may not be able to successfully foster adoption of our products and services.

Our technologies are new and complex, and are subject to change as new discoveries are made. New discoveries and advancements in the diagnostic field are essential if we are to foster the adoption of our product offerings. Development of our existing technologies remains a substantial risk to us due to various factors, including the scientific challenges involved, our ability to find and collaborate successfully with others working in the diagnostic field, and competing technologies, which may prove more successful than our technologies.

We may not succeed in developing additional diagnostic products, and, even if we do succeed in developing additional diagnostic products, the diagnostic products may never achieve significant commercial market acceptance.

Our success depends on our ability to continue to develop and commercialize diagnostic products. There is considerable risk in developing diagnostic products based on our biomarker discovery efforts, as candidate biomarkers may fail to validate results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. For example, markers being evaluated for one or more next-generation ovarian cancer diagnostic tests may not be validated in downstream pre-clinical or clinical studies, once we undertake and perform such studies. In addition, development of products combining biomarkers with imaging, patient risk factors or other risk indicators carry higher than average risks due to technical, clinical and regulatory uncertainties. While we have published proof of concept on combining OVA1 and imaging, for example, our ability to develop, verify and validate an algorithm that generalizes to routine testing populations cannot be guaranteed. If successful, the regulatory pathway and clearance/approval process may require extensive discussion with applicable authorities and possibly, medical panels or other oversight mechanisms. These pose considerable risk in projecting launch dates, requirements for clinical evidence and eventual pricing and return on investment. Although we are engaging important stakeholders representing gynecologic oncology, benign gynecology, patient advocacy, women's health research, reimbursement and others, success, timelines and value will be uncertain and require active management at all stages of innovation and development.

Clinical testing is expensive, takes many years to complete and can have an uncertain outcome. Clinical failure can occur at any stage of the testing. Clinical trials for our next generation ovarian cancer tests, and other future diagnostic tests, may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing on these tests. In addition, the results of our clinical trials may identify unexpected risks relative to safety or efficacy, which could complicate, delay or halt clinical trials, or result in the denial of regulatory approval by the FDA and other regulatory authorities.

If we do succeed in developing additional diagnostic tests with acceptable performance characteristics, we may not succeed in achieving commercial market acceptance for those tests. Our ability to successfully commercialize diagnostic products, including OVA1, will depend on many factors, including:

- our ability to convince the medical community of the safety and clinical efficacy of our products and their advantages over existing diagnostic products;

- our success in establishing new clinical practices or changing previous ones, such that utilization of the tests fail to meet established standards of care, medical guidelines and the like;

- our ability to develop business relationships with diagnostic or laboratory companies that can assist in the commercialization of these products in the U.S. and globally; and

- the scope and extent of the agreement by Medicare and third-party payers to provide full or partial reimbursement coverage for our products, which will affect patients' willingness to pay for our products and will likely heavily influence physicians' decisions to recommend or use our products.

These factors present obstacles to commercial acceptance of our existing and potential diagnostic products, for which we will have to spend substantial time and financial resources to overcome, and there is no guarantee that we will be successful in doing so. Our inability to do so successfully would prevent us from generating revenue from OVA1 and future diagnostic products.

The diagnostics market is competitive, and we may not be able to compete successfully, which would adversely impact our ability to generate revenue.

Our principal competition currently comes from the many clinical options available to medical personnel involved in clinical decision making. For example, rather than ordering an OVA1 test for a woman with an adnexal mass, obstetricians, gynecologists, and gynecologic oncologists may choose a different clinical option or none at all. If we are not able to convince clinicians that OVA1 provides significant improvement over current clinical practices, our ability to commercialize OVA1 will be adversely affected. Additionally, in September 2011, Fujirebio Diagnostics received FDA clearance for its ROMA test. ROMA combines two tumor markers and menopausal status into a numerical score using a publicly available algorithm. This test has the same intended use and precautions as OVA1, and our revenues could be materially and adversely affected if the ROMA test is successfully commercialized. In addition, competitors, such as Becton Dickinson, ArrayIt Corporation, and Abbott Laboratories have publicly disclosed that they have been or are currently working on ovarian cancer diagnostic assays. Academic

institutions periodically report new findings in ovarian cancer diagnostics that may have commercial value. Our failure to compete with any competitive diagnostic assay if and when commercialized could adversely affect our business, financial condition and results of operations.

We have priced OVA1 at a point that recognizes the value-added by its increased sensitivity for ovarian malignancy. If others develop a test that is viewed to be similar to OVA1 in efficacy but is priced at a lower point, we and/or our strategic partners may have to lower the price of OVA1 in order to effectively compete, which would impact our margins and potential for profitability.

Our diagnostic tests are subject to ongoing regulation by the FDA; the commercialization of our diagnostic tests may be adversely affected by changing FDA regulations; and any delay by or failure of the FDA to approve our diagnostic tests submitted to the FDA may adversely affect our business, results of operations and financial condition.

The FDA cleared OVA1 in September 2009. In connection with the clearance of OVA1 we agreed to conduct certain post-market surveillance studies to further analyze performance of OVA1 in pre- and post-menopausal women. Failure to comply with our post-marketing study requirements may lead to enforcement actions by the FDA, including seizure of our product, injunction, prosecution and/or civil money penalties, which may harm our business, results of operations and financial condition.

Our activities related to diagnostic products are, or have the potential to be, subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of our products. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

The Federal Food, Drug and Cosmetic Act requires that medical devices introduced to the United States market, unless exempted by regulation, be the subject of either a pre-market notification clearance, known as a 510(k) clearance or 510(k) de novo clearance, or a pre-market approval (“PMA”). Some of our potential future clinical products may require a 510(k) or 510(k) de novo clearance, while others may require a PMA. With respect to devices reviewed through the 510(k) process, we may not market a device until an order is issued by the FDA finding our product to be substantially equivalent to a legally marketed device known as a predicate device. A 510(k) submission may involve the presentation of a substantial volume of data, including clinical data. The FDA may agree that the product is substantially equivalent to a predicate device and allow the product to be marketed in the United States. On the other hand, the FDA may determine that the device is not substantially equivalent and require a PMA or a de novo 510(k), or require further information, such as additional test data, including data from clinical studies, before it is able to make a determination regarding substantial equivalence. By requesting additional information, the FDA can delay market introduction of our products. Delays in receipt of or failure to receive any necessary 510(k) clearance or PMA approval, or the imposition of stringent restrictions on the labeling and sales of our products, could have a material adverse effect on our business, results of operations and financial condition. If the FDA indicates that a PMA is required for any of our potential future clinical products, the application will require extensive clinical studies, manufacturing information and likely review by a panel of experts outside the FDA. Clinical studies to support either a 510(k) submission or a PMA application would need to be conducted in accordance with FDA requirements. Failure to comply with FDA requirements could result in the FDA’s refusal to accept the data or the imposition of regulatory sanctions. We cannot assure that any necessary 510(k) clearance or PMA approval will be granted on a timely basis, or at all. To the extent we seek FDA 510(k) clearance or FDA pre-market approval for other diagnostic tests, any delay by or failure of the FDA to clear or approve those diagnostic tests may adversely affect our consolidated revenues, results of operations and financial condition.

If we or our suppliers fail to comply with FDA requirements for production, marketing and post-market monitoring of our products, we may not be able to market our products and services and may be subject to stringent penalties, product restrictions or recall; further improvements to our manufacturing operations may be required that could entail additional costs.

The commercialization of our products could be delayed, halted or prevented by applicable FDA regulations. If the FDA were to view any of our actions as non-compliant, it could initiate enforcement actions, such as a warning letter and possible imposition of penalties. For instance, we are subject to a number of FDA requirements, including compliance with the FDA's Quality System Regulations "QSR" requirements, which establish extensive requirements for quality assurance and control as well as manufacturing procedures. Failure to comply with these regulations could result in enforcement actions for us or our potential suppliers. Adverse FDA actions in any of these areas could significantly increase our expenses and reduce our revenue. We will need to undertake steps to maintain our operations in line with the FDA's QSR requirements. Some components of OVA1 are manufactured by other companies and we are required to ensure that, to the extent that we incorporate those components into our finished OVA1 test, we use those components in compliance with QSR. Any failure to do so would have an adverse effect on our ability to commercialize OVA1. Our suppliers' manufacturing facilities, since they manufacture finished kits that we use in OVA1, are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. Our facility also is subject to FDA inspection. We or our suppliers may not satisfy such regulatory requirements, and any such failure to do so may adversely affect our business, financial condition and results of operations.

If our suppliers fail to produce acceptable or sufficient stock, make changes to the design or labeling of their biomarker kits or discontinue production of existing biomarker kits or instrument platforms, we may be unable to meet market demand for OVA1.

The commercialization of our OVA1 test depends on the supply of five different immunoassay kits from third-party manufacturers run on automated instruments. Failure by any of these manufacturers to produce kits that pass Vermillion's quality control measures might lead to back-order and/or loss of revenue due to missed sales and customer dissatisfaction. In addition, if the design or labeling of any kit were to change, continued OVA1 supply could be threatened since new validation and submission to the FDA for 510(k) clearance could be required as a condition of sale. Discontinuation of any of these kits would require identification, validation and 510(k) submission on a revised OVA1 design. Likewise, discontinuation or failure to support or service the instruments may pose risk to ongoing operations.

Effective December 2014, one of the five immunoassay component kits that are used in OVA1 ceased to be supported on the instrument as the manufacturer transitioned to a newer platform. While we have not experienced and do not anticipate disruption of ongoing operations, failure of the manufacturer to provide extended service or support might harm our business. Overa consolidates the five OVA1 immunoassays onto a single mainstream automated platform and substitutes a new immunoassay component kit for the discontinuing kit as a mitigating action. However, we have not yet received a 510(k) clearance from the FDA for Overa. No assurances can be made that the FDA will clear our 510(k) submission, which was made in March 2015. Any resulting disruption to our supply of OVA1 may adversely affect our business, financial condition and results of operations.

If we fail to maintain our rights to utilize intellectual property directed to diagnostic biomarkers, we may not be able to offer diagnostic tests using those biomarkers.

One aspect of our business plan is to develop diagnostic tests based on certain biomarkers, which we have the right to utilize through licenses with our academic collaborators, such as Johns Hopkins University School of Medicine and the University of Texas M.D. Anderson Cancer Center. In some cases, our collaborators own the entire right to the biomarkers. In other cases, we co-own the biomarkers with our collaborators. If, for some reason, we lose our license to biomarkers owned entirely by our collaborators, we may not be able to use those biomarkers in diagnostic tests. If we lose our exclusive license to biomarkers co-owned by us and our collaborators, our collaborators may license their share of the intellectual property to a third party that may compete with us in offering diagnostic tests, which would materially adversely affect our business, results of operations and financial condition.

If a third party infringes on our proprietary rights, we may lose any competitive advantage we may have as a result of diversion of our time, enforcement costs and the loss of the exclusivity of our proprietary rights.

Our success depends in part on our ability to maintain and enforce our proprietary rights. We rely on a combination of patents, trademarks, copyrights and trade secrets to protect our technology and brand. We have

submitted a number of patent applications covering biomarkers that may have diagnostic or therapeutic utility. Our patent applications may or may not result in additional patents being issued.

If third parties engage in activities that infringe on our proprietary rights, we may incur significant costs in asserting our rights, and the attention of our management may be diverted from our business. We may not be successful in asserting our proprietary rights, which could result in our patents being held invalid or a court holding that the competitor is not infringing, either of which may harm our competitive position. We cannot be sure that competitors will not design around our patented technology.

We also rely upon the skills, knowledge and experience of our technical personnel. To help protect our rights, we require all employees and consultants to enter into confidentiality agreements that prohibit the disclosure of confidential information. These agreements may not provide adequate protection for our trade secrets, knowledge or other proprietary information in the event of any unauthorized use or disclosure. If any trade secret, knowledge or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, it could have a material adverse effect on our business, consolidated results of operations and financial condition.

If others successfully assert their proprietary rights against us, we may be precluded from making and selling our products or we may be required to obtain licenses to use their technology.

Our success depends on avoiding infringing on the proprietary technologies of others. If a third party were to assert claims that we are violating its patents, we might incur substantial costs defending ourselves in lawsuits against charges of patent infringement or other unlawful use of another’s proprietary technology. Any such lawsuit may involve considerable management and financial resources and may not be decided in our favor. If we are found liable, we may be subject to monetary damages or an injunction prohibiting us from using the technology. We may also be required to obtain licenses under patents owned by third parties and such licenses may not be available to us on commercially reasonable terms, if at all.

Future litigation against us could be costly and time consuming to defend.

We are from time to time subject to legal proceedings and claims that arise in the ordinary course of business, such as claims brought by our clients in connection with commercial disputes, employment claims made by current or former employees, and claims brought by third parties alleging infringement of their intellectual property rights. In addition, we may bring claims against third parties for infringement of our intellectual property rights. Litigation may result in substantial costs and may divert our attention and resources, which may adversely affect our business, results of operations and financial condition.

An unfavorable judgment against us in any legal proceeding or claim could require us to pay monetary damages. In addition, an unfavorable judgment in which the counterparty is awarded equitable relief, such as an injunction, could harm our business, results of operations and financial condition.

Our diagnostic efforts may cause us to have significant product liability exposure.

The testing, manufacturing and marketing of medical diagnostic tests entail an inherent risk of product liability claims. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. We will need to increase our amount of insurance coverage in the future if we are successful at introducing new diagnostic products, and this will increase our costs. If we are held liable for a claim or for damages exceeding the limits of our insurance coverage, we may be required to make substantial payments. This may have an adverse effect on our business, financial condition and results of operations.

Because our business is highly dependent on key executives and employees, our inability to recruit and retain these people could hinder our business plans.

We are highly dependent on our executive officers and certain key employees. Our executive officers and key employees are employed at will by us. Any inability to engage new executive officers or key employees could impact operations or delay or curtail our research, development and commercialization objectives. To continue our research and product development efforts, we need people skilled in areas such as clinical operations, regulatory affairs and clinical diagnostics. Competition for qualified employees is intense.

If we lose the services of any executive officers or key employees, our ability to achieve our business objectives could be harmed, which in turn could adversely affect our business, financial condition and results of operations.

Business interruptions could limit our ability to operate our business.

Our operations, as well as those of the collaborators on which we depend, are vulnerable to damage or interruption from fire; natural disasters, including earthquakes; computer viruses; human error; power shortages; telecommunication failures; international acts of terror; and similar events. Although we have certain business continuity plans in place, we have not established a formal comprehensive disaster recovery plan, and our back-up operations and business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

Legislative actions resulting in higher compliance costs may adversely affect our business, financial condition and results of operations.

Compliance with laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, and new regulations adopted by the SEC, are resulting in increased compliance costs. We, like all other public companies, are incurring expenses and diverting employees' time in an effort to comply with Section 404 of the Sarbanes-Oxley Act of 2002. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations. Compliance with these evolving standards will result in increased general and administrative expenses and may cause a diversion of our time and attention from revenue-generating activities to compliance activities.

Changes in healthcare policy could increase our costs and impact sales of and reimbursement for our tests.

In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"). Pursuant to the PPACA, beginning in 2013, each medical device manufacturer has paid a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. The PPACA also mandated a reduction in payments of 1.75% for the years 2011 through 2015 for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule. This adjustment was in addition to a productivity adjustment to the Clinical Laboratory Fee Schedule. In April 2014, President Barack Obama signed the Protecting Access to Medicare Act of 2014, which halted certain reductions in payment mandated by the PPACA as well as certain CMS policies, and will instead establish a market-based reimbursement system for clinical laboratories beginning in 2017 and require reporting of certain private payer reimbursement data by laboratories beginning in 2016. CMS also issued various regulations and guidance generally effective January 1, 2014 that limited reimbursement for clinical laboratory tests as a general matter, but permitted the continued ability for CMS to pay for Multianalyte Assays with Algorithmic Analyses in certain circumstances. In addition to these changes, a number of states are also contemplating significant reform of their healthcare policies. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by the PPACA have resulted in decreased profits to us and lower reimbursements by payers for our tests. Other changes to healthcare laws may adversely affect our business, financial condition and results of operations.

We are subject to environmental laws and potential exposure to environmental liabilities.

We are subject to various international, federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, the recycling and treatment of electrical and electronic equipment, and emissions and discharges into the environment. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We are also subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs to remediate hazardous substances or petroleum products on or

from its property, without regard to whether the owner or operator knew of, or caused, the contamination, as well as incur liability to third parties affected by such contamination. The presence of, or failure to remediate properly, such substances could adversely affect the value and the ability to transfer or encumber such property.

The success of ASPiRA LABS depends, in part, on our ability to generate sufficient demand for its services to cover the laboratory's operating costs, and there is no assurance that we will be able to do so successfully.

The launch of our new clinical laboratory, ASPiRA LABS, involves significant costs to us, including the costs of laboratory equipment and facilities, outside consulting fees for branding and other services and other general and administrative expenses. We expect to continue to incur significant costs to operate ASPiRA LABS in the future, such as salaries and related expenses for personnel, regulatory compliance costs and ongoing costs of outsourced billing services. There is no guarantee that we will be able to generate a sufficient volume of patients to access the laboratory and utilize its offerings to cover the fixed and ongoing costs of ASPiRA LABS.

Revenue from ASPiRA LABS has been minimal to date, and there is no guarantee that we be able to generate sufficient revenue in the future to offset our costs. Our inability to successfully develop sufficient demand for the diagnostic tests processed by the laboratory could delay or prevent ASPiRA LABS from generating material revenue, and we may not achieve revenues or profitability from ASPiRA LABS in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our ASPiRA LABS operations or we may be unable to expand our offerings at ASPiRA LABS beyond ovarian cancer to other gynecologic conditions with high unmet need as we intend.

The launch of ASPiRA LABS requires us to comply with numerous laws and regulations, which is expensive and time-consuming and could adversely affect our business, financial condition and results of operations, and any failure to comply could result in exposure to substantial penalties and other harm to our business.

In June 2014, we launched a clinical laboratory, ASPiRA LABS. Clinical laboratories that perform tests on human subjects in the United States for the purpose of providing information for the diagnosis, prevention or treatment of disease must be certified under CLIA and licensed under applicable state laboratory laws. CLIA regulates the quality of clinical laboratory testing by requiring laboratories to comply with various technical, operational, personnel and quality requirements intended to ensure that the services provided are accurate, reliable and timely. State laws may require that additional quality standards be met and that detailed review of scientific validations and technical procedures for tests occur.

We received our temporary CLIA Certificate of Registration effective February 18, 2014 and, as of the date of this Quarterly Report on Form 10-Q, we have obtained a full Certificate of Accreditation and state laboratory licensure from certain states. We are subject to periodic surveys and inspections to maintain our CLIA certification, and such certification is also required to obtain payment from Medicare, Medicaid and certain other third-party payers. Failure to comply with CLIA or state law requirements may result in the imposition of corrective action or the suspension or revocation of our CLIA certification or state licenses. If our CLIA certification or state licenses are suspended or revoked or our right to bill the Medicare and Medicaid programs or other third-party payers is suspended, we would no longer be able to sell our tests, which would adversely affect our business, financial condition and results of operations.

In addition, no assurance can be given that ASPiRA LABS' suppliers or commercial partners will remain in compliance with applicable CLIA and other federal or state regulatory requirements for laboratory operations and testing. ASPiRA LABS' facilities and procedures and those of ASPiRA LABS' suppliers and commercial partners are subject to ongoing regulation, including periodic inspection by regulatory and other government authorities. Possible regulatory actions for non-compliance could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of ASPiRA LABS' products, and criminal prosecution.

Our clinical laboratory business is also subject to regulation at both the federal and state level in the United States, as well as regulation in other jurisdictions outside of the United States, including:

• Medicare and Medicaid coverage, coding and payment regulations applicable to clinical laboratories;

• the Federal Anti Kickback Statute and state anti-kickback prohibitions;

• the federal physician self-referral prohibition, commonly known as the Stark Law, and state self-referral prohibitions;

• the Medicare civil monetary penalty and exclusion requirements;

• the Federal False Claims Act civil and criminal penalties and state equivalents; and

• the Federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”);

Many of these laws and regulations prohibit a laboratory from making payments or furnishing other benefits to influence the referral of tests (by physicians or others) that are billed to Medicare, Medicaid or certain other federal or state healthcare programs. The penalties for violation of these laws and regulations may include monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Several states have similar laws that may apply even in the absence of government payers. HIPAA and HITECH and similar state laws seek to protect the privacy and security of individually identifiable health information, and penalties for violations of these laws may include required reporting of breaches, monetary fines and criminal or civil penalties.

While we seek to conduct our business in compliance with all applicable laws and develop compliance policies to address risk as appropriate, many of the laws and regulations applicable to us are vague or indefinite and have not been interpreted by governmental authorities or the courts. These laws or regulations also could in the future be interpreted or applied by governmental authorities or the courts in a manner that could require us to change our operations.

Any action brought against us for violation of these or other laws or regulations (including actions brought by private qui tam “whistleblower” plaintiffs), even if successfully defended, could divert management’s attention from our business, damage our reputation, limit our ability to provide services, decrease demand for our services and cause us to incur significant expenses for legal fees and damages. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal penalties, fines, recoupment of funds received by us, exclusion from participation in federal or state healthcare programs, and the loss of various licenses, certificates and authorizations necessary to operate our business. We also could potentially incur additional liabilities from third-party claims. If any of the foregoing were to occur, it could have a material adverse effect on our business, financial condition and results of operations.

In the future, we plan to develop and perform LDTs at ASPiRA LABS. If the FDA finalizes its October 3, 2014 draft guidance documents that outline the FDA’s proposal to actively regulate LDTs, we may need to obtain a 510(k) clearance or pre-market approval for our future LDTs, and there is no guarantee that we would ever procure the

needed FDA clearance or approval. We also would need to comply with ongoing regulatory requirements.

We intend to develop and perform LDTs at ASPiRA LABS. The FDA has historically exercised enforcement discretion and not required approvals or clearances for LDTs. However, on October 3, 2014, the FDA issued two draft guidance documents, entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)” and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs),” respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs.

According to the draft guidance documents, all laboratories with LDTs—except for those only performing forensic testing or certain LDTs for transplantation—would need to comply with some basic statutory requirements, regardless of the risks of the tests, including adverse event reporting, corrections and removals reporting and registration and listing or notification.

In addition, “high” and “moderate” risk tests not subject to an exemption will need to be the subject of a PMA or 510(k) submitted to the FDA in a phased-in manner. High-risk tests are those that are classified as Class III devices. Within those high-risk devices, the FDA identifies the “highest risk devices” as (1) LDTs with the same

intended use as an approved or cleared companion diagnostic; (2) LDTs with the same intended use as an FDA-approved Class III device; and (3) certain LDTs for determining safety and effectiveness of blood or blood products. Moderate-risk tests are those that are classified as Class II devices. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and, if so, how the final framework might differ from the proposal. In addition, the new regulatory requirements are proposed to be phased in consistent with the schedule set forth in the guidance documents for tests that are on the market at the time the guidance documents are finalized.

Legislative proposals addressing the FDA's oversight of LDTs have been previously introduced, and we expect that new legislative proposals will be introduced from time to time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate LDTs as medical devices is difficult to predict.

Even before the FDA finalizes such guidance documents, the FDA may assert that a test that we believe to be an LDT is not an LDT and could require us to seek clearance or approval to offer such tests for clinical use. If the FDA pre-market review or approval is required for any of the future LDTs we may develop, we may be forced to stop selling our tests or be required to modify claims or make such other changes while we work to obtain FDA clearance or approval. Our business, results of operations and financial condition would be negatively affected until such review is completed and clearance to market or approval is obtained.

If pre-market review is required by the FDA or if we decide to voluntarily pursue FDA pre-market review of our future LDTs, there can be no assurance that any tests we develop in the future will be cleared or approved on a timely basis, if at all. Obtaining FDA clearance or approval for diagnostics can be expensive, time consuming and uncertain, and for higher-risk devices generally takes several years and requires detailed and comprehensive scientific and clinical data. In addition, medical devices are subject to ongoing FDA obligations and continued regulatory oversight and review. Ongoing compliance with FDA regulations for those tests would increase the cost of conducting our business and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

Risks Related to Owning Our Stock

The liquidity and trading volume of our common stock may be low, and our ownership is concentrated.

The liquidity and trading volume of our common stock has at times been low in the past and may again be low in the future. If the liquidity and trading volume of our common stock is low, this could adversely impact the trading price of our shares, our ability to issue stock and our stockholders' ability to obtain liquidity in their shares. The issuance of common stock by us in May 2013 and subsequent warrant exercise in December 2013, the issuance of common stock by us in December 2014 and the issuance of common stock by us in July 2015, involved a significant issuance of stock to a limited number of investors, significantly increasing the concentration of our share ownership in a few holders.

According to information provided on Schedules 13D and 13G, five persons beneficially owned approximately 62% of our outstanding shares of common stock as of September 30, 2015, and under a May 2013 stockholders agreement, two of these persons have certain rights to designate a director to be nominated by us to serve on the Board of Directors. As a result, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the

interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock.

Our stock price has been, and may continue to be, highly volatile.

The trading price of our common stock has been highly volatile and could continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- failure to significantly increase revenue and volumes of OVA1;
- actual or anticipated period-to-period fluctuations in financial results;
- failure to achieve, or changes in, financial estimates by securities analysts;
- announcements or introductions of new products or services or technological innovations by us or our competitors;
- publicity regarding actual or potential discoveries of biomarkers by others;
- comments or opinions by securities analysts or stockholders;
- conditions or trends in the pharmaceutical, biotechnology or life science industries;
- announcements by us of significant acquisitions and divestitures, strategic partnerships, joint ventures or capital commitments;
- developments regarding our patents or other intellectual property or that of our competitors;
- litigation or threat of litigation;
- additions or departures of key personnel;
- limited daily trading volume;
- economic and other external factors, disasters or crises; and
- our announcement of additional fundraisings.

In addition, the stock market in general and the market for diagnostic technology companies, in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of our attention and our resources.

Anti-takeover provisions in our charter, bylaws, other agreements and under Delaware law could make a third party acquisition of the Company difficult.

Certain provisions of our certificate of incorporation and bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us, even if a change of control might be deemed beneficial to our stockholders. Such provisions could limit the price that certain investors might be willing to pay in the future for our securities. Our certificate of incorporation eliminates the right of stockholders to call special meetings of stockholders or to act by written consent without a meeting, and our bylaws require advance notice for stockholder proposals and director nominations, which may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders. Our certificate of incorporation also authorizes undesignated preferred stock, which makes it possible for our board of directors, without stockholder approval, to issue preferred stock with voting or other rights or preferences that could adversely affect the voting power of holders of common stock. In addition, the likelihood that the holders of preferred stock will receive dividend payments and payments upon liquidation could have the effect of delaying, deferring or preventing a change in control.

In connection with our private placement offering of common stock and warrants on May 13, 2013, we entered into a stockholders agreement which, among other things, includes agreements limiting our ability to effect a change in control without the consent of at least one of the two primary investors in that offering. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of us. The amendment of any of the provisions of either our certificate of incorporation or bylaws described in the preceding paragraph would require not only approval by our board of directors and the affirmative vote of at least 66 2/3% of our then outstanding voting securities, but also the consent of at least one of the two primary investors in

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the May 2013 offering. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company. These provisions could make a third-party acquisition of the Company difficult and limit the price that investors might be willing to pay in the future for shares of our common stock.

We could face adverse consequences as a result of the actions of activist stockholders.

Certain of our stockholders may, from time to time, attempt to aggressively involve themselves in the governance and strategic direction of our Company above and apart from normal interactions between stockholders and management. Such activism, and any related negative publicity, could result in substantial costs that negatively impact our stock price and increase its volatility. In addition, such activism could cause a diversion of the attention of our management and Board of Directors and create perceived uncertainties with existing and potential strategic partners impacting our ability to consummate potential transactions, collaborations or opportunities in furtherance of our strategic plan. In addition, such activism could make it more difficult to attract and retain qualified personnel, customers and business partners, which could disrupt the growth of the market for OVA1, delay the development and commercialization of new tests and further adversely affect the trading price of our common stock and increase its volatility. In addition, the activists may have little or no experience in the diagnostics industry or may seek to elect members to our Board of Directors with little or no experience in the diagnostics industry who may have a specific agenda different and apart from the majority of our stockholders.

Because we do not intend to pay dividends, our stockholders will benefit from an investment in our common stock only if it appreciates in value.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our stockholders purchased their shares.

We may need to sell additional shares of our common stock or other securities in the future to meet our capital requirements, which could cause significant dilution.

As of September 30, 2015, we had 52,009,716 shares of our common stock outstanding and 3,427,693 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 3,319,623 shares of our common stock that were subject to outstanding options. In addition, as of September 30, 2015, warrants to purchase 4,608,018 shares of our common stock were outstanding. These warrants are exercisable at the election of the holders thereof at an average exercise price of $1.96 per share.

The exercise of all or a portion of our outstanding options and warrants will dilute the ownership interests of our stockholders. Furthermore, future sales of substantial amounts of our common stock in the public market, or the perception that such sales are likely to occur, could affect prevailing trading prices of our common stock.

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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					(1)
31.2	Certification of the Chief Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					(1)
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)

Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act and is otherwise not subject to liability under these sections.

(1) Furnished herewith

SIGNATURES

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

Vermillion, Inc.

Date: November 12, 2015 /s/ Valerie B. Palmieri
Valerie B. Palmieri

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 12, 2015 /s/ Eric J. Schoen
Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)