VERMILLION, INC.
Form 10-Q
November 13, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 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, 2014

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-34810

Vermillion, Inc.
(Exact name of registrant as specified in its charter)

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

(512) 519-0400

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically 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 (Do not check if a smaller reporting company)	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, 2014, the registrant had 36,020,987 shares of common stock, par value $0.001 per share, outstanding.

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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, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 16,762	$ 29,504
Accounts receivable	179	373
Prepaid expenses and other current assets	936	372
Total current assets	17,877	30,249
Property and equipment, net	530	391
Total assets	$ 18,407	$ 30,640
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,144	$ 541
Accrued liabilities	2,078	1,283
Short-term debt	1,106	1,106
Deferred revenue	1,504	628
Total current liabilities	5,832	3,558
Deferred revenue	—	316
Total liabilities	5,832	3,874
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2014 and December 31, 2013, respectively	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized at September 30, 2014 and December 31, 2013; 35,962,514 and 35,825,673 shares issued and		

outstanding at September 30, 2014 and December 31, 2013, respectively	36	36
Additional paid-in capital	359,936	358,994
Accumulated deficit	(347,397)	(332,264)
Total stockholders' equity	12,575	26,766
Total liabilities and stockholders' equity	$ 18,407	$ 30,640

See accompanying notes to the 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,	
	2014	2013	2014	2013
Revenue:				
Product	$ 209	$ 216	$ 611	$ 640
License	114	114	341	341
Total revenue	323	330	952	981
Cost of revenue:				
Product	606	25	749	96
Total cost of revenue	606	25	749	96
Gross profit (loss)	(283)	305	203	885
Operating expenses:				
Research and development(1)	1,263	553	3,473	1,591
Sales and marketing(2)	2,762	1,180	7,632	3,172
General and administrative(3)	1,281	889	4,240	3,160
Total operating expenses	5,306	2,622	15,345	7,923
Loss from operations	(5,589)	(2,317)	(15,142)	(7,038)
Interest income	8	7	34	15
Other income (expense), net	(10)	(4)	(25)	21
Loss before income taxes	(5,591)	(2,314)	(15,133)	(7,002)
Income tax benefit (expense)	—	—	—	—
Net loss	$ (5,591)	$ (2,314)	$ (15,133)	$ (7,002)
Net loss per share - basic and diluted	$ (0.16)	$ (0.10)	$ (0.42)	$ (0.36)
Weighted average common shares used to compute basic and diluted net loss per common share	35,913,580	23,486,496	35,865,089	19,472,105
Non-cash stock-based compensation expense included in operating expenses:				
(1) Research and development	$ 32	$ 12	$ 103	$ 44
(2) Sales and marketing	164	32	233	118
(3) General and administrative	159	22	518	143

See accompanying notes to the consolidated financial statements.

Vermillion, Inc.

Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	$ (15,133)	$ (7,002)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash license revenue	(341)	(341)
Depreciation and amortization	93	55
Stock-based compensation expense	832	281
Warrants issued for services	22	24
Changes in operating assets and liabilities:		
Accounts receivable	194	(29)
Prepaid expenses and other assets	(564)	121
Accounts payable, accrued liabilities and other liabilities	1,398	308
Deferred revenue	901	905
Net cash used in operating activities	(12,598)	(5,678)
Cash flows from investing activities:		
Purchase of property and equipment	(232)	—
Net cash used in investing activities	(232)	—
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	-	11,751
Proceeds from issuance of common stock from exercise of stock options	88	524
Net cash provided by financing activities	88	12,275
Net increase (decrease) in cash and cash equivalents	(12,742)	6,597
Cash and cash equivalents, beginning of period	29,504	8,007
Cash and cash equivalents, end of period	$ 16,762	$ 14,604
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ —	$ —

See accompanying notes to the 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") develops and commercializes diagnostic tests for gynecologic disease. In March 2010, the Company commercially launched the OVA1® ovarian tumor triage test ("OVA1"). The Company distributes OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics"), a related party (see Note 3) and through our wholly-owned CLIA certified clinical laboratory, ASPiRA LABS, Inc ("ASPiRA"), which opened on June 23, 2014. The terms "Vermillion," "the Company," "we," "us," and "our" refer to Vermillion and its wholly-owned subsidiaries as whole, unless the context otherwise requires.

Liquidity

There can be no assurance that the Company 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's operations.

Our management believes that the current working capital position will be sufficient to meet the Company's working capital needs for at least the next 12 months. However, our management also believes that the successful achievement of our business objectives will require additional financing. We expect to raise capital through a variety of sources, which may include the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and/or public or private debt.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants and potential 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 on terms acceptable to us. 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 current activity.

Our management expects cash from OVA1 sales to be the Company's only material, recurring source of cash through the balance of 2014 and into 2015.

Basis of Presentation

The accompanying unaudited 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 Rule 10-01 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, 2013 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, 2013, included in Vermillion's Annual Report on Form 10-K which was filed with the Securities and Exchange Commission (the "SEC") on March 31, 2014.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimated results.

Significant Accounting and Reporting Policies

The Company has 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, 2013 except as discussed below:

Revenue Recognition

Product Revenue: The Company derives product revenues from sales of OVA1 through Quest Diagnostics and ASPiRA. Product revenues are recognized for tests performed when the following revenue recognition criteria are met: (1) persuasive

evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

As the Company has not established sufficient payment history with the insurance companies or private payors for the tests performed at ASPiRA, payment is not fixed or determinable and collectability is not reasonably assured, and we will defer recognizing revenues until those criteria are met, which typically coincides with the collection of cash. Once we establish a reliable payment history, we plan to return to normal accrual revenue recognition based on our criteria discussed above.

2. NEW ACCOUNTING PRONOUNCEMENTS

In August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-15, "Presentation of Financial Statements – Going Concern," (ASU 2014-15). ASU 2014-15 provides guidance with regard to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. This ASU clarified that management should perform its evaluation whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The accounting standard is effective for annual periods ending after December 15, 2016 and interim periods thereafter. Early adoption is permitted. The adoption of this standard is not expected to have a material effect on our financial statements.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period," (ASU 2014-12). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in ASU 2014-12 are effective for annual periods and interim periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of this standard is not expected to have a material effect on our financial statements.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers," (ASU 2014-09), which creates a new Topic, Accounting Standards Codification Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The accounting standard is effective for annual and interim periods beginning after December 15, 2016. Early adoption is

not permitted. We are currently evaluating the impact of adopting this guidance.

3. STRATEGIC ALLIANCE AND SECURED LINE OF CREDIT WITH QUEST DIAGNOSTICS INCORPORATED

Quest Diagnostics is a holder of the Company's common stock. In July 2005, the Company entered into a Strategic Alliance Agreement (as amended, the "Strategic Alliance Agreement") with Quest Diagnostics to develop and commercialize up to three diagnostic tests from the Company's product pipeline. In connection with the Strategic Alliance Agreement, the Company entered into a credit agreement with Quest Diagnostics, pursuant to which Quest Diagnostics provided the Company with a $10,000,000 secured line of credit collateralized by certain intellectual property assets of the Company. Pursuant to the Strategic Alliance Agreement, Quest Diagnostics selected two diagnostic tests to be commercialized, a peripheral arterial disease diagnostic test and OVA1. 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. If not otherwise forgiven, the $10,000,000 principal amount outstanding under this secured line of credit became due and payable in October 2012. Through September 30, 2014, a total of $3,000,000 has been acknowledged as forgiven by Quest Diagnostics based upon milestone achievement.

The Company believes that, in September 2009, when the United States Food and Drug Administration (the "FDA") cleared the Company's application for a licensed laboratory test of OVA1 to be commercialized, the Company achieved a milestone under the credit agreement, resulting in a $1,000,000 reduction of the outstanding principal amount borrowed under the credit agreement. However, Quest Diagnostics has disputed whether this milestone has been achieved.

In September 2009, the Company achieved another milestone under the credit agreement, resulting in a $3,000,000 further reduction in the principal amount borrowed under the credit agreement. Although the Company believed that, following this reduction, the principal balance under the line of credit was $6,000,000, the Company made monthly payments to Quest Diagnostics on the secured line of credit based on a principal balance of $7,000,000, resulting in a curtailment of the principal balance of $106,000. However, Quest Diagnostics has disputed that such additional principal curtailment was made.

In October 2012, the Company paid Quest Diagnostics approximately $5,894,000 of principal which the Company believes represented payment in full of all then outstanding principal under the secured line of credit. However, the Company continues to show the amount of the liability as $1,106,000 as of September 30, 2014 because Quest Diagnostics has disputed that the $1,000,000 milestone was met and the $106,000 principal curtailment was made.

Unrelated to the debt dispute described above, in May 2013, the Company sent Quest Diagnostics a notice of default under the Strategic Alliance Agreement relating to a number of its material violations, breaches and failures to perform under the Strategic Alliance Agreement. The Strategic Alliance Agreement states that if a party fails to cure material defaults within 90 days of the date of the notice of default, the other party has the right to terminate the Strategic Alliance Agreement. In August 2013, the Company sent Quest Diagnostics a notice of termination. Notwithstanding the termination, the Company agreed that Quest Diagnostics can 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. 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 11, 2014, with the right to extend the exclusivity period for one additional year. Quest Diagnostics has disputed the effectiveness of the Company's notice of termination.

4. COMMITMENT AND CONTINGENCIES

The Company leases facilities located in Austin, Texas with an annual base rent of $83,000 and annual estimated common area charges, taxes and insurance of $39,000. The primary lease expires on May 31, 2016.

5. STOCKHOLDERS' EQUITY

Equity Offering

In October 2014, the Company established an at-the-market offering program, pursuant to which we may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $15.0 million. The Company will pay a commission of up to 3.0% of the gross proceeds from the sale of shares of Company common stock in the offering. The Company is not obligated to sell any shares of Company common stock in the offering.

Stock Option Exercises

During the three and nine months ended September 30, 2014, options to purchase 40,988 and 52,091 shares of Vermillion common stock were exercised for total proceeds to the Company of $68,400 and $87,500, respectively.

2010 Stock Incentive Plan

The Company's employees, directors, and consultants are eligible to receive awards under the Amended and Restated Vermillion, Inc. 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 3,622,983 shares of common stock, par value $0.001 per share, under the 2010 Plan, subject to adjustment as provided in the 2010 Plan.

Employee Stock-Based Compensation

During the three and nine months ended September 30, 2014, the Company awarded none and 152,000 shares of restricted stock under the 2010 Plan having a fair value of approximately $470,000 to Vermillion's Board of Directors as payment for services in 2014. Rights to 48,500 shares of restricted stock were subsequently forfeited or contractually waived by Vermillion directors during the nine months ended September 30, 2014. The remaining shares of restricted stock vested 50% on June 1, 2014 and 25% on September 1, 2014 with the remaining 25% vesting on December 1, 2014.

In January 2014, the Company granted options to purchase 151,500 shares of Company common stock with an exercise price of $2.88 per share to Vermillion's Chairman of the Board of Directors. These stock options vest over a four year period with 25% of the stock options vesting on December 12, 2014 and the balance in 36 equal monthly installments thereafter. On April 23, 2014, the Company granted options to purchase 348,500 shares of Company common stock with an exercise price of $2.90 per share to Vermillion's President, Chief Executive Officer and Chairman of the Board of Directors. These stock options vest in 48 equal monthly installments from the date of the grant.

During the nine months ended September 30, 2014, the Company also granted to certain other Vermillion officers and employees (a) options to purchase approximately 422,000 shares of Company common stock with an exercise price of $3.09 per share which vest in 48 equal monthly installments from the date of the grant and (b) options to purchase 22,500 shares of Company common stock with an exercise price of $2.87 per share, options to purchase 251,000 shares of Company common stock with an exercise price of $2.21 per share and options to purchase 100,000 shares of Company common stock with an exercise price of $2.05 per share all of which vest over a four year period with 25% of the options vesting on the employee's one year anniversary and the balance in 36 equal monthly installments thereafter.

In October 2014, the Company granted a Vermillion officer options to purchase 175,000 shares of Company common stock with an exercise price of $1.55 per share which vest in 48 equal monthly installments from the date of the grant.

The allocation of employee stock-based compensation expense by functional area for the three and nine months ended September 30, 2014 and 2013 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2014	2013	2014	2013
Research and development	$ 32	$ 12	$ 103	$ 42
Sales and marketing	164	32	233	118
General and administrative	159	9	483	119
Total	$ 355	$ 53	$ 819	$ 279

6. 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 common shares outstanding and excludes the effects of 2,563,106 and 13,330,302 potential common shares as of September 30, 2014 and 2013, respectively, that are antidilutive. Potential common shares include incremental shares of common stock issuable upon the exercise of outstanding warrants, stock options, and restricted stock awards.

7. RELATED PARTY TRANSACTIONS

Quest Diagnostics is a stockholder and was the holder of the Company’s secured line of credit (see Note 3). Accounts receivable from Quest Diagnostics under the Strategic Alliance Agreement totaled $179,000 and $373,000 at September 30, 2014 and December 31, 2013, respectively.

On October 23, 2014, the Company appointed Valerie Palmieri as Chief Operating Officer ("COO"). Vermillion was party to a consulting agreement with a company owned by the COO to provide laboratory operations and commercialization consulting services to Vermillion. The Company made payments of $340,000 for services provided pursuant to the consulting agreement through September 30, 2014. The consulting agreement was terminated as of October 23, 2014. In connection with the work performed under the consulting agreement, the Company granted Ms. Palmieri 15,000 shares of restricted stock under the 2010 Plan having a fair value of approximately $31,000 for achievement of certain milestones.

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," similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements speak only as of the date on which this report is filed with the SEC, and the Company does not assume any obligation to update, amend or clarify them to reflect events, new information or circumstances after such date. Forward-looking statements are subject to risks, uncertainties and assumptions that are difficult to predict. Examples of forward-looking statements regarding our business include the following:

- projections of or expectations regarding our future revenue, results of operations and financial condition;
- 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;
- anticipated efficacy of our products, product development activities and product innovations;
- our expected ability to consolidate the five OVA1 immunoassays on a single mainstream integrated diagnostic automation platform;
- expected competition and consolidation in the markets in which we compete;
- plans with respect to ASPiRA LABS, Inc. ("ASPiRA LABS");
- expectations regarding existing and future collaborations and partnerships;
- our belief that particular biomarker discoveries may have diagnostic and/or therapeutic utility;
- achieving milestones in product development, future regulatory or scientific submissions and presentations;

- our continued ability to comply with applicable governmental regulations;
- our continued ability to expand and protect our intellectual property portfolio;
- anticipated future losses;
- expected levels of expenditures;
- expected market adoption of our diagnostic tests, including OVA1;
- anticipated results of clinical trials, post-market studies required by FDA, and publications on OVA1;
- the amount of financing anticipated to be required to fund our planned operations;
- our prospects for obtaining support of medical or professional societies (e.g., Society for Gynecologic Oncology ("SGO"), National Comprehensive Cancer Network ("NCCN") and American Congress of Obstetricians and Gynecologists ("ACOG")) through "guidelines", "position statements" and the like;
- the financial or market share projections which could result from positive guidelines or position statements; and
- our expected reimbursement for our products, and our expected ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans.

Forward-looking statements are subject to significant risks and uncertainties, including those discussed in Part II, Item 1A "Risk Factors" of this quarterly report on Form 10-Q and our quarterly report on Form 10-Q for the quarter ended March 31, 2014 and those discussed in Part I, Item 1A "Risk Factors" of our annual report on Form 10-K for the year ended December 31, 2013, 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; uncertainty in how we recognize future revenue following termination of the Quest Diagnostics Strategic Alliance Agreement; 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 OVA1 outside the United States; 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 for our future diagnostic products; our suppliers' ability to comply with FDA requirements for production, marketing and post market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; our ability to continue to develop, protect and promote our proprietary technologies; future litigation against us, including infringement of intellectual property and product liability exposure; our ability to retain key employees; business interruptions; legislative actions resulting in higher compliance costs; changes in healthcare policy; our ability to comply with environmental laws; our ability to market CA125II; uncertainty regarding our ability to generate sufficient demand for ASPiRA LABS' services to cover the laboratory's operating costs; uncertainty regarding our ability to comply with laws and regulations (including the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS) and the potential consequences of any failure to comply with such laws and regulations; the potentially low liquidity and trading volume of our common stock and concentration in the ownership of our common stock; volatility in the price of our common stock; actions of activist stockholders; and potential dilution caused by future sale of our common stock or other securities to meet our capital requirements. Readers should not put undue reliance on any forward-looking statement. We believe it is important to communicate our expectations to our investors. However, there may be events in the future that we are not able to accurately predict or that we do not fully control that could cause actual results to differ materially from those expressed or implied in our forward-looking statements.

Overview

Our vision is to drive the advancement of women's health by providing innovative methods to detect, monitor and manage the treatment of gynecologic disease – both benign and malignant cancers and other related diseases including

both benign and malignant conditions.

We have expanded our corporate strategy with the goal of transforming Vermillion from a diagnostic company to a bio-analytic solutions provider. Working in three phases, we plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders. The three phases are a rebuild phase, which is occurring during the second half of 2014, a transformation phase, which we expect to span 2015, and a market expansion and growth phase, which we expect to begin in 2016. During the first phase, we hired a new head of sales and managed markets, a new head of marketing, a new head of operations and a new chief medical 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 plan to obtain licensure of ASPiRA LABS in all 50 states, establish our own payer coverage for OVA1, launch a second generation OVA1 (predicated on receipt of FDA approval) and demonstrate proof of concept for a laboratory development test ("LDT") product series, which we refer to internally as OvaX. OvaX includes not only biomarkers but also clinical risk factors and patient history data in order to boost predictive value. In the third phase, we plan to focus on market expansion and growth.

We are dedicated to the discovery, development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Our OVA1 and soon-to-be marketed CA125II tests are intended 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 modality data, clinical risk factors and patient data into a single, reportable index score that has higher diagnostic accuracy than its constituents. We concentrate on our development of novel diagnostic tests for gynecologic disease, with an initial focus on ovarian cancer. We also intend to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and others through collaborations with leading academic and research institutions.

Our lead product, OVA1, is a blood test designed to identify women who are at high risk of having a malignant ovarian tumor prior to surgery. The United States Food and Drug Administration (the "FDA") cleared OVA1 in September 2009 and we commercially launched OVA1 in March 2010. We have completed development work on a second-generation bio-marker panel intended to maintain our product's high sensitivity while improving specificity. We have successfully completed development of the second-generation product and are currently validating the results for a planned submission to the FDA in early 2015, with the goal of launching in the second half of 2015. The product will use the Roche Cobas platform.

On June 23, 2014, Vermillion launched ASPiRA LABS, which specializes in applying biomarker-based technologies, including OVA1, to address critical needs in the management of gynecologic cancers. ASPiRA LABS provides expert diagnostic processing and results using a state-of-the-art biomarker-based diagnostic algorithm to inform clinical decision making and advance personalized treatment plans. In addition, ASPiRA LABS, a Clinical Laboratory Improvement Amendments ("CLIA") certified national lab based near Austin, Texas, seeks to serve as an educational and resource hub for healthcare professionals and women facing surgery for ovarian masses that are potentially cancerous and related gynecologic conditions. The lab currently processes our OVA1 test, a diagnostic test and clinical decision aid for women's health in ovarian cancer, and we expect the lab to process the CA 125II test in the future. We plan to expand the testing provided by the lab to other gynecologic conditions with high unmet need. We also plan to develop and perform LDTs at ASPiRA LAB. ASPiRA began accepting samples on June 23, 2014. ASPiRA currently holds a Certificate of Registration under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and a state laboratory license in California and Rhode Island. ASPiRA is in the process of obtaining state licensure in New York, Florida, Maryland and Pennsylvania.

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 expanding our direct market reach beyond our business relationship with Quest Diagnostics and taking the lead in commercialization, payer coverage and commercialization of OVA1. This strategy includes the launch of a CLIA certified clinical laboratory, ASPiRA LABS, in June 2014 and the plan to begin transitioning Quest Diagnostics volume to ASPiRA LABS in 2015;

- Improving OVA1 performance by seeking FDA clearance of a potentially better performing bio-marker panel while migrating OVA1 to a global testing platform – 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 a persistent adnexal mass condition.

We believe that these business drivers will contribute significantly to addressing unmet medical needs for women faced with gynecologic disease and other conditions and the continued development of our business.

OVA1 addresses a clear clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary software cleared as part of the OVA1 510(k) to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary testing, surgery and/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.

In 2012, we completed a second pivotal clinical study of OVA1 called the "OVA500 study," led by Dr. Robert E. Bristow, Director of Gynecologic Oncology Services with University of California Irvine Healthcare. The study evaluated OVA1 diagnostic performance in a population of 494 evaluable patients who underwent surgery for an adnexal mass after enrollment by a non-gynecologic oncologist. In February 2013, the OVA500 study was published in the peer-reviewed journal Gynecologic Oncology, which we believe enjoys the highest impact factor rating of any journal worldwide focused on gynecologic oncology. Since many professional medical societies stress the importance of multiple independent clinical trials as so-called "evidence levels", we also believe that the OVA500 study contributes to a higher evidence level relative to OVA1's utility in the medical management of adnexal masses.

In addition to these pivotal studies, three follow-on studies have been published bringing the number of full research articles on OVA1 clinical performance to a total of five peer-reviewed publications. Together, we believe these data provide strong clinical evidence that OVA1, in conjunction with the physician's independent clinical and radiological evaluation, improves the pre-surgical detection of ovarian cancer, across all stages or subtypes, in patients undergoing surgery for a suspicious ovarian mass.

The American Medical Association Current Procedural Terminology ("CPT®") Panel approved a Category I CPT code (81503) for OVA1, which became effective in January 2013.

Dr. Bristow presented another study at the Society of Gynecological Oncology ("SGO") in March 2013 which was published in the journal Obstetrics & Gynecology (also known as the Green Journal) in June 2013. This study was based on the medical records of 13,321 women with epithelial cancer, the most common type of ovarian cancer, diagnosed from 1999 to 2006 in California. Only 37 percent of these patients received treatment that adhered to guidelines set by the National Comprehensive Cancer Network ("NCCN"), an alliance of 23 major cancer centers with expert panels that analyze, research and recommend cancer treatments. The study found that surgeons who operated on 10 or more women a year for ovarian cancer, and hospitals that treated 20 or more a year, were more likely to adhere to NCCN guidelines and their patients lived longer. Among women with advanced disease — the stage at which ovarian cancer is usually first found — 35 percent survived at least five years if their care met the guidelines, compared with 26 percent of those whose care fell short.

In May 2013, the SGO issued a new position statement on OVA1. This second SGO statement on OVA1 since its FDA clearance in 2009 represents another significant step toward acceptance of OVA1 as the standard of care for pre-surgically evaluating the risk of ovarian cancer in women with adnexal masses. The statement, titled "Multiplex Serum Testing for Women with Pelvic Mass", reads:

"Blood levels of five proteins in women with a known ovarian mass have been reported to change when ovarian cancer is present. Tests measuring these proteins may be useful in identifying women who should be referred to a gynecologic oncologist. Recent data have suggested that such tests, along with physician clinical assessment, may improve detection rates of malignancies among women with pelvic masses planning surgery. [1],[2] Results from such tests should not be interpreted independently, nor be used in place of a physician's clinical assessment. Physicians are strongly encouraged to reference the American Congress of Obstetricians and Gynecologists' 2011 Committee Opinion "The Role of the Obstetrician-Gynecologist in the Early Detection of Epithelial Ovarian Cancer" to determine an appropriate care plan for their patients. It is important to note that no such test has been evaluated for use as, nor cleared by, the FDA as a screening tool for ovarian cancer. SGO does not formally endorse or promote any specific products or brands."

[1] Bristow RE, Smith A, Zhang Z, Chan DW, Crutcher G, Fung ET, et al. Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. Gynecol Oncol 2013;128: 252–259

[2] Ueland FR, Desimone CP, Seamon LG, Miller RA, Goodrich S, Podzielinski I, et al. Effectiveness of a multivariate index assay in the preoperative assessment of ovarian tumors. Obstet Gynecol 2011;117:1289-1297."

We believe the position statement does two things:

- Lists as references the publications of OVA1's two pivotal clinical studies, comprised of the original FDA validation study published in June 2011 and the OVA500 "intended use" study published in 2013. Together, this offers an extensive, peer-reviewed proof source for physicians and payers to assess OVA1's clinical performance and comparative medical benefits versus today's standard of care.

- Places OVA1 use in the context of current ACOG practice guidelines, where CA125 has been used off-label for many years to predict malignancy before surgery, although with inferior performance.

A study published in July 2014 in The American Journal of Obstetrics & Gynecology, examined the relationship between two imaging methods, ultrasound and computed tomography, and the OVA1 test result in assessing the risk of ovarian cancer among patients planning surgery for an ovarian mass. Using data obtained from 1,100 ovarian mass surgery patients in two previous pivotal trials of OVA1's clinical performance, conducted in 2007 and 2012, the study found that adding OVA1 reduced the number of ovarian

cancers missed with imaging alone by 84-90%. Specifically, ultrasound alone missed 23.1% of ovarian cancers that were presented but when OVA1 was added in parallel, the number of ovarian cancers missed decreased to 2.2%. When CT was used alone, 20.2% of ovarian cancers were missed but this rate fell to 2.9% when OVA1 was added in parallel. Additionally, the study found when ultrasound and OVA1 were combined in parallel, 95% of ovarian cancers in a subgroup of early-stage patients were detected.

Novitas Solutions (formerly Highmark Medicare Services), a Medicare contractor, covers and reimburses for OVA1. In December 2013, the Centers for Medicare and Medicaid Services ("CMS") made its final determination and authorized Medicare contractors to set prices for Multianalyte Assays with Algorithmic Analyses ("MAAA") test CPT codes when they determine it is payable. CMS also validated that an algorithm has unique value by specifying that the gap-fill process and not cross-walk should be used by contractors to price MAAA tests. We expect OVA1 to be priced using the gap-fill method. We will be engaged in that process in 2015 for pricing effective January 1, 2016. This decision also sets a precedent for recognizing the value of biomarker developed tests to clinical decision-making and healthcare efficiencies.

Under the terms of our Strategic Alliance Agreement with Quest Diagnostics, which we terminated in August 2013, Quest Diagnostics was required to pay us a fixed payment of $50 per OVA1 test performed, as well as 33% of its "gross margin" from revenue from performing OVA1 tests domestically, as that term is defined in the Strategic Alliance Agreement. Prior to the termination of the 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 US, Mexico, the United Kingdom and India. This right extended through September 11, 2014 and Quest Diagnostics had the right to extend its exclusivity period for an additional year on the same terms and conditions. In August 2013, we sent Quest Diagnostics a notice of termination. Notwithstanding the termination, we 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 has disputed the effectiveness of our notice of termination. We have been in active discussions with Quest Diagnostics for some time on both settling our contract dispute and creating a new go-forward relationship. We believe that we may be able to reach a negotiated settlement by the end of 2014.

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, 2013 except as discussed below:

Revenue Recognition

Product Revenue: The Company derives product revenues from sales of OVA1 through Quest Diagnostics and ASPiRA LABS. Product revenues are recognized for tests performed when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

As the Company has not established sufficient payment history with the insurance companies or private payors for the tests performed at ASPiRA LABS, payment is not fixed or determinable and collectability is not reasonably assured, and we will defer recognizing revenues until those criteria are met, which typically coincides with the collection of cash. Once we establish a reliable payment history, we plan to return to normal accrual revenue recognition based on our criteria discussed above.

Results of Operations - Three Months Ended September 30, 2014 Compared to Three Months Ended September 30, 2013

The selected summary financial and operating data of Vermillion for the three months ended September 30, 2014 and 2013 were as follows:

	Three Months Ended September 30,		Increase (Decrease)	
(dollars in thousands)	2014	2013	Amount	%
Revenue:				
Product	$ 209	$ 216	$ (7)	(3)
License	114	114	—	—
Total revenue	323	330	(7)	(2)
Cost of revenue:				
Product	606	25	581	2,324
Total cost of revenue	606	25	581	2,324
Gross profit (loss)	(283)	305	(588)	(193)
Operating expenses:				
Research and development	1,263	553	710	128
Sales and marketing	2,762	1,180	1,582	134
General and administrative	1,281	889	392	44
Total operating expenses	5,306	2,622	2,684	102
Loss from operations	(5,589)	(2,317)	(3,272)	141
Interest income	8	7	1	14
Other expense, net	(10)	(4)	(6)	150
Loss before income taxes	(5,591)	(2,314)	(3,277)	142
Income tax benefit (expense)	—	—	—	—
Net loss	$ (5,591)	$ (2,314)	$ (3,277)	142

Product Revenue. Product revenue was $209,000 for the three months ended September 30, 2014 compared to $216,000 for the same period in 2013. We recognized product revenue for the sale of OVA1 only through Quest Diagnostics at the $50 fixed fee per test during both periods. The number of OVA1 tests performed was approximately 4,325 OVA1 tests during the three months ended September 30, 2014 compared to approximately 4,328 OVA1 tests for the same period in 2013. Product revenue was consistent quarter over quarter.

Cost of Revenue. Cost of product revenue for the three months ended September 30, 2014 increased $581,000 compared to the same period in 2013. Cost of product revenue for the three months ended September 30, 2014 includes $575,000 for costs of ASPiRA LABS incurred after the lab began accepting test samples on June 23, 2014 and includes approximately $200,000 of non-recurring lab start-up costs.

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, 2014 increased $710,000 or 128% compared to the same period in 2013. This increase was primarily due to increased efforts in the third quarter of 2014 associated with our collaboration with Johns Hopkins University School of Medicine to complete development work for our platform migration and next-generation diagnostic test. In addition, we have an increased research and development headcount compared to the same period in 2013.

Sales and Marketing Expenses. Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses increased $1,582,000 or 134%, for the three months ended September 30, 2014 compared to the same period in 2013. The increase was primarily due to increased personnel and personnel-related expenses from our sales force expansion in April 2014 as well as costs incurred in the establishment and branding of ASPiRA LABS in 2014 compared to the same period in 2013. We also incurred a one-time $211,000 cost of severance for our former Senior Vice President, Sales and Marketing.

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 $392,000 or 44%, for the three months ended September 30, 2014 compared to the same period in 2013. The increase was primarily due to costs for non-recurring consulting fees.

Results of Operations - Nine Months Ended September 30, 2014 Compared to Nine Months Ended September 30, 2013

The selected summary financial and operating data of Vermillion for the nine months ended September 30, 2014 and 2013 were as follows:

	Nine Months Ended September 30,		Increase (Decrease)	
(dollars in thousands)	2014	2013	Amount	%
Revenue:				
Product	$ 611	$ 640	$ (29)	(5)
License	341	341	—	—
Total revenue	952	981	(29)	(3)
Cost of revenue:				
Product	749	96	653	680
Total cost of revenue	749	96	653	680
Gross profit	203	885	(682)	(77)
Operating expenses:				
Research and development	3,473	1,591	1,882	118
Sales and marketing	7,632	3,172	4,460	141
General and administrative	4,240	3,160	1,080	34
Total operating expenses	15,345	7,923	7,422	94
Loss from operations	(15,142)	(7,038)	(8,104)	115
Interest income	34	15	19	127
Other income (expense), net	(25)	21	(46)	(219)
Loss before income taxes	(15,133)	(7,002)	(8,131)	116
Income tax benefit (expense)	—	—	—	—
Net loss	$ (15,133)	$ (7,002)	$ (8,131)	116

Product Revenue. Product revenue was $611,000 for the nine months ended September 30, 2014 compared to $640,000 for the same period in 2013. We recognized product revenue for the sale of OVA1 only through Quest Diagnostics at the $50 fixed fee per test during both periods. The number of OVA1 tests performed decreased 3.4% to approximately 12,365 OVA1 tests during the nine months ended September 30, 2014 compared to approximately 12,786 OVA1 tests for the same period in 2013.

Cost of Revenue. Cost of product revenue for the nine months ended September 30, 2014 increased $653,000 compared to the nine months ended September 30, 2013. Cost of product revenue for the nine months ended September 30, 2014 includes $624,000 for costs of ASPiRA LABS after the lab began accepting samples on June 23, 2014, including approximately $200,000 of non-recurring lab start-up costs.

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, 2014 increased $1,882,000, or 118% compared to the same period in 2013. This increase was primarily due to increased efforts during 2014 associated with our collaboration with Johns Hopkins University School of Medicine advancing our platform migration and next-generation diagnostic test. In addition, we increased research and development headcount compared to the same period in 2013.

Sales and Marketing Expenses. Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses increased $4,460,000, or 141%, for the nine months ended September 30, 2014 compared to the same period in 2013. The increase was primarily due to increased personnel and personnel-related expenses from our sales force expansion in April 2014 as well as costs incurred in the establishment and branding of ASPiRA LABS in 2014 compared to the same period in 2013. We also incurred a one-time $211,000 cost of severance for our former Senior Vice President, Sales and Marketing and expenses for health economic and outcomes studies during the nine months ended September 30, 2014. There were no such expenses in the comparable period in 2013.

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 $1,080,000, or 34%, for the nine months ended September 30, 2014 compared to the same period in 2013. The change was primarily due to a one-time $416,000 cost of severance for our former President and Chief Executive Officer,

$552,000 of pre-opening costs incurred for ASPiRA LABS prior to June 23, 2014 (the opening date for ASPiRA LABS) and costs of non-recurring consulting fees.

Liquidity and Capital Resources

In October 2014, the Company established an at-the-market offering program, pursuant to which we may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $15.0 million. The Company will pay a commission of up to 3.0% of the gross proceeds from the sale of shares of Company common stock in the offering. The Company is not obligated to sell any shares of Company common stock in the offering.

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, 2014, we had an accumulated deficit of $347,397,000 and stockholders' equity of $12,575,000. As of September 30, 2014, we had $16,762,000 of cash and cash equivalents and $5,832,000 of current liabilities.

There can be no assurance that the Company will achieve or sustain profitability or positive cash flow from operations. In addition, while we expect to grow revenue with the addition of ASPiRA LABS, there is no assurance of our ability to generate substantial revenues and cash flows from ASPiRA LABS operations.

Our management believes that the current working capital position will be sufficient to meet the Company's working capital needs for at least the next 12 months. However, our management also believes that the successful achievement of our business objectives will require additional financing. We expect to raise capital through a variety of sources, which may include the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and/or public or private debt.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants and potential 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 on terms acceptable to us. 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 current activity.

Our management expects cash from OVA1 sales to be the Company's only material, recurring source of cash through the balance of 2014 and into 2015.

Cash and cash equivalents as of September 30, 2014 and December 31, 2013, were $16,762,000 and $29,504,000, respectively. Working capital was $12,045,000 and $26,691,000 at September 30, 2014 and December 31, 2013, respectively.

Net cash used in operating activities was $12,598,000 for the nine months ended September 30, 2014 compared to $5,678,000 for the nine months ended September 30, 2013. The increase in net cash used in operating activities resulted primarily from an increase in net loss reported of $15,133,000 for the nine months ended September 30, 2014 compared to $7,002,000 for the comparable period in 2013 partially offset by changes in operating assets and liabilities including a $1,398,000 increase in accounts payable and accrued liabilities.

Net cash used by investing activities for the nine months ended September 30, 2014 was $232,000 related to the purchases of property and equipment. There was no net cash used in investing activities for the nine months ended September 30, 2013.

Net cash provided by financing activities for the nine months ended September 30, 2014 was $88,000 which consists of proceeds from stock option exercises. Net cash provided by financing activities for the nine months ended September 30, 2013 was $12,275,000 which resulted from the $11,751,000 net proceeds from our May 2013 private placement as well as $524,000 from proceeds from issuance of common stock from the exercise of stock options.

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

We had significant net operating loss ("NOL") credit carryforwards as of September 30, 2014 for which a full valuation allowance has been provided due to our history of operating losses. Our ability to use our 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, 2014, 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, 2014. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of September 30 2014, 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 adversely affect our results of operations, cash flows or 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, 2014, that, in the opinion of management, will have a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

There have been no material changes to our risk factors previously disclosed under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10 K for the year ended December 31, 2013 except for those risk factors disclosed under "Risk Factors" in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, which are hereby incorporated herein by reference and set forth below:

Our diagnostic tests are subject to ongoing regulation by the FDA, and 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 study 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 FDA, including seizure of our product, injunction, prosecution, and/or civil money penalties, which may irreparably harm our business.

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 warning or untitled letters, withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

The 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 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.

In the future, we plan to develop and perform LDTs at ASPiRA LABS. If the FDA proceeds with its plans to actively regulate laboratory-developed tests, we might need to obtain a 510(k) clearance or PMA for our future LDTs, and there is no guarantee that we would ever procure the needed FDA clearance or approval.

We intend to develop and perform laboratory-developed tests ("LDTs") at ASPiRA LABS. The FDA has historically exercised enforcement discretion and not required approvals or clearances for LDTs. However, on July 31, 2014, the FDA notified Congress of its intent to issue two draft guidance documents regarding oversight of LDTs. If the FDA were to issue and finalize those draft guidances, depending on the level of risk of the test, a laboratory might have to submit a PMA as early as 12 months after the guidance is finalized, could be exempt from premarket review altogether, or have to submit a PMA or 510(k) sometime after 12 months after the guidance is finalized.

The FDA's proposed framework in the notification to Congress also outlines post-market controls including registration and listing or FDA notification, compliance with the Quality System Regulations ("QSR") requirements, and adverse event reporting that will be required of all LDTs except those for forensic (law enforcement) use and transplantation. In addition, the FDA has indicated that if a laboratory runs a test that has received a 510(k) clearance in a manner that is different from the instructions for use, then the FDA will consider that changed test to be an LDT.

Even before the FDA finalizes such guidance, 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 our tests for clinical use. If the FDA premarket 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 other

changes while we work to obtain FDA clearance or approval. Our business would be negatively affected until such review is completed and clearance to market or approval is obtained.

If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our future LDTs, there can be no assurance that any tests we may develop in the future will be cleared or approved on a timely basis, if at all. 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.

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	
10.1	Terms of Modified Participation Rights Relating to ATM	S-3/A	333-198734	4.9	September 30, 2014	
10.2	Amended and Restated Employment Agreement, effective April 23, 2014, by and between Vermillion, Inc. and James T. LaFrance#	10-Q	001-34810	10.1	August 14, 2014	
10.3	Employment Agreement, effective as of September 2, 2014, by and between Vermillion, Inc. and Holly Bauzon #	8-K	001-34810	10.1	August 21, 2014	
10.4	Employment Agreement, effective as of October 23, 2014 by and between Vermillion, Inc. and Valerie Palmieri #	8-K	001-34810	99.1	October 28, 2014	
10.5	Sales Agreement, dated September 12, 2014, by and between Vermillion, Inc. and Cantor Fitzgerald & Co.	S-3	333-198734	1.1	September 15, 2014	
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					
31.2	Certification of the Chief Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					
32.1						(1)

	Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (1)
101	Interactive Data Files

(1) Furnished herewith

Management contracts or compensatory plan or arrangement.

SIGNATURES

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

Vermillion, Inc.

Date: November 13, 2014 /s/ James T. LaFrance
James T. LaFrance

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 13, 2014 /s/ Eric J. Schoen
Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)