VERMILLION, INC.
Form 10-Q
May 12, 2015
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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 March 31, 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	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 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 April 30, 2015, the Registrant had 43,115,790 shares of common stock, par value $0.001 per share, outstanding.

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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)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 17,241	$ 22,965
Accounts receivable	160	167
Prepaid expenses and other current assets	684	526
Total current assets	18,085	23,658
Property and equipment, net	492	508
Other assets	98	8
Total assets	$ 18,675	$ 24,174
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,295	$ 1,123
Accrued liabilities	2,190	2,201
Short-term debt	—	1,106
Deferred revenue	—	489
Total liabilities	3,485	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 March 31, 2015 and December 31, 2014, respectively	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized at March 31, 2015 and December 31, 2014; 43,115,790 shares issued and outstanding at March 31, 2015 and December 31, 2014	43	43
Additional paid-in capital	370,757	370,685
Accumulated deficit	(355,610)	(351,473)
Total stockholders' equity	15,190	19,255
Total liabilities and stockholders' equity	$ 18,675	$ 24,174

See accompanying notes to the unaudited consolidated financial statements.

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Vermillion, Inc.

Consolidated Statements of Operations

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

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Product	$ 635	$ 191
License	316	114
Total revenue	951	305
Cost of revenue:		
Product	491	55
Gross profit	460	250
Operating expenses:		
Research and development(1)	1,105	1,153
Sales and marketing(2)	2,217	2,104
General and administrative(3)	1,400	988
Total operating expenses	4,722	4,245
Loss from operations	(4,262)	(3,995)
Interest income	9	14
Other income (expense), net	116	(6)
Net loss	$ (4,137)	$ (3,987)
Net loss per share - basic and diluted	$ (0.10)	$ (0.11)
Weighted average common shares used to compute basic and diluted net loss per common share	43,115,790	35,827,886
Non-cash stock-based compensation expense included in operating expenses:		
(1) Research and development	$ 31	$ 40
(2) Sales and marketing	37	25
(3) General and administrative	97	69

See accompanying notes to the unaudited consolidated financial statements.

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Vermillion, Inc.

Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (4,137)	$ (3,987)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt	(78)	-
Non-cash license revenue	(316)	(114)
Depreciation and amortization	53	27
Stock-based compensation expense	165	123
Warrants issued for services	-	11
Changes in operating assets and liabilities:		
Accounts receivable	7	204
Prepaid expenses and other assets	(248)	(356)
Accounts payable, accrued liabilities and other liabilities	202	318
Deferred revenue	(173)	269
Net cash used in operating activities	(4,525)	(3,505)
Cash flows from investing activities:		
Purchase of property and equipment	(37)	(19)
Net cash used in investing activities	(37)	(19)
Cash flows from financing activities:		
Issuance costs from sale of common stock and warrants	(93)	-
Repayment of short-term debt	(1,069)	-
Proceeds from issuance of common stock from exercise of stock options	-	11
Net cash (used in)/provided by financing activities	(1,162)	11
Net decrease in cash and cash equivalents	(5,724)	(3,513)
Cash and cash equivalents, beginning of period	22,965	29,504
Cash and cash equivalents, end of period	$ 17,241	$ 25,991

See accompanying notes to the unaudited consolidated financial statements.

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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™ ovarian tumor triage test ("OVA1"). The Company distributes OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics") (see Note 2) and through its wholly-owned Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, Inc. ("ASPiRA LABS"), which opened on June 23, 2014.

Liquidity

The Company expects cash for OVA tests to be its only material, recurring source of cash in 2015. 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. If the Company is unable to obtain additional capital over the next year, it may be required to delay, reduce the scope of or eliminate key research and development activities, including a planned registry study, which would eliminate or delay our plans to launch future products. This could have a material adverse effect on the Company's business, results of operations and financial condition.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants and dilution to stockholders. If the Company obtains additional funds through arrangements with collaborators or strategic partners, it may be required to relinquish its rights to certain technologies or products that it might otherwise seek to retain. Additional funding may not be available when needed or on terms acceptable to the Company.

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, 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.

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2. AGREEMENTS 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 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 $78,000 and reversal of other liabilities totaling $37,000.

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, we reached a settlement agreement with Quest Diagnostics that terminated all disputes related to our prior strategic alliance and loan agreements. We also entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, as amended on April 10, 2015 (the "New Quest Agreement"), Vermillion's wholly-owned subsidiary, ASPiRA LABS, will begin to offer OVA1 testing to Quest Diagnostics customers. We expect Quest Diagnostics to transfer all OVA1 U.S. testing services to ASPiRA LABS, starting with 49 states this year, while continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing through March 11, 2017. Pursuant to the New Quest Agreement, Quest Diagnostics will also continue to offer OVA1 services through its own labs in the remaining state, until ASPiRA LABS has obtained the state approvals required to provide those services. Quest will receive a fee for collection and logistic support services it provides. Per the terms of the New Quest Agreement, we will not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers.

Accounts receivable from Quest Diagnostics under the Strategic Alliance Agreement totaled $160,000 and $167,000 at March 31, 2015 and December 31, 2014, respectively.

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. Vermillion leases its principal facility and CLIA laboratory located near Austin, Texas. The leases include an 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.

In April 2015, the Company agreed to purchase 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.

4. STOCKHOLDERS' EQUITY

2010 Stock Incentive Plan

The Company's employees, directors, and consultants are eligible to receive awards under the Vermillion, Inc. 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 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 months ended March 31, 2015, the Company granted 400,000 stock options with an exercise price of $1.95 per share to the Company's President and Chief Executive Officer. These stock options vest in 48 equal monthly installments from the date of the grant. The Company also granted 275,000 stock options with an exercise price of $2.08 to certain Vermillion officers and

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45,000 stock options with an exercise price of $1.77 to certain Vermillion employees. 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.

On April 1, 2015, the Company granted 150,000 stock options with an exercise price of $1.74 per share to a Vermillion officer. 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. The April 1, 2015 grant is subject to stockholder approval of an increase of 4,500,000 in the number of shares authorized to be granted under the 2010 Plan. Pursuant to Accounting Standards Codification 718, “Compensation – Stock Compensation,” there is no stock-based compensation expense recognized for this stock option grant until approval by the Company’s stockholders of an increase in the number of shares authorized under the 2010 Plan.

The allocation of employee stock-based compensation expense by functional area for the three months ended March 31, 2015 and 2014 was as follows:

	Three Months Ended March 31,	
(in thousands)	2015	2014
Research and development	$ 31	$ 40
Sales and marketing	37	25
General and administrative	97	58
Total	$ 165	$ 123

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 common shares outstanding and excludes the effects of 7,040,587 and 2,616,490 potential common shares as of March 31, 2015 and 2014, respectively, that are anti-dilutive. Potential common shares 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 report is filed with the Securities and Exchange Commission (the "SEC"), and, except as required by law, Vermillion, Inc. ("Vermillion" and, together with its subsidiaries, the "Company", "we", "our" or "us") does n assume any obligation to update, amend or clarify them to reflect events, new information or circumstances occurring after such date. Examples of language found in forward-looking statements include the following:

- projections or expectations regarding our future revenue, 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;
- 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;
- plans with respect to ASPiRA LABS, Inc., our wholly-owned subsidiary ("ASPiRA LABS"), including plans regarding the migration of OVA1 testing from Quest Diagnostics Incorporated ("Quest Diagnostics") to ASPiRA LABS, and obtaining the requisite state licensure to support this migration;
- plans with respect to OVA2 and OvaX;
- plans to develop and implement laboratory development tests ("LDTs") at ASPiRA LABS;
- expectations regarding existing and future collaborations and partnerships;

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- achieving milestones in product development and pending regulatory submissions;
- our ability to commercialize OVA1 in other countries;
- anticipated future losses and our ability to continue as a going concern;
- expected levels of expenditures;
- expected market adoption of our diagnostic tests, including OVA1;
- the amount of financing anticipated to be required to fund our planned operations; and
- our expected reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans.

Forward-looking statements are subject to significant risks and uncertainties, including those discussed in Part I, Item 1A “Risk Factors” of our annual report on Form 10-K for the year ended December 31, 2014, 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 including ASPiRA LABS; 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; in the event that we succeed in commercializing OVA1 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; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; our ability to continue to develop, protect and promote our proprietary technologies; future litigation against us, including infringement of intellectual property and product liability exposure; our ability to retain key employees; business interruptions; legislative actions resulting in higher compliance costs; changes in healthcare policy; our ability to comply with environmental laws; our ability to generate sufficient demand for ASPiRA LABS’ services to cover its operating costs; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; and our ability to obtain any FDA clearance or approval required to develop and perform LDTs. 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

Corporate Vision: 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 as well as other gynecologic diseases.

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 we expect to complete in the third quarter of 2015, a transformation phase, which is ongoing and is expected to span 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, operations, a chief medical officer, a chief information 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 plan to obtain licensure of ASPiRA LABS in all 50 states, establish our own payer coverage for OVA1 and launch a second-generation OVA1 test, known as OVA2 (predicated on receipt of FDA approval). In the third phase, we plan to commercialize OVA2 by utilizing the full national licensure of ASPiRA LABS, managed care coverage in select markets, our sales force and existing customer base. Unlike OVA1, OVA2 uses a global testing platform, which will allow OVA2 to be deployed internationally. We also plan to demonstrate proof of concept for a LDT product series, which we refer to internally as OvaX. We anticipate that OvaX will include not only biomarkers, but also clinical risk factors and patient history data in order to boost predictive value.

Mission Statement: 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

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detection, treatment response, monitoring of disease progression, prognosis and others through collaborations with leading academic and clinical research institutions.

Strategy:

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 current commercial agreement with Quest Diagnostics and taking the lead in payer coverage and commercialization of OVA1. This strategy includes the launch of a Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical laboratory, ASPiRA LABS, in June 2014;

- Improving OVA1 performance by seeking FDA clearance of a potentially better performing biomarker panel while migrating OVA1 to a global testing platform, thus 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.

Business:

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 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 intended to maintain our product's high sensitivity while improving specificity. We submitted our 510(k) clearance application to the FDA on March 6, 2015, with the goal of commencing the marketing and sale of the panel in the second half of 2015. The product uses the Roche Cobas platform.

OVA1 addresses a clear clinical need, namely the presurgical 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 presurgical 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 June 2014, Vermillion launched ASPiRA LABS, a 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. 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. In addition, ASPiRA LABS, seeks to serve as an educational and resource hub for healthcare professionals and women facing surgery for potentially-cancerous ovarian masses and other related gynecologic conditions. The lab currently processes our OVA1 test, and we expect the lab to process the CA 125-II test 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 currently holds a temporary CLIA Certificate of Registration and a state laboratory license in California and Rhode Island. ASPiRA LABS is in the process of obtaining a full Certificate of Accreditation and state laboratory licensure in New York, Maryland and Pennsylvania. The Centers for Medicare and Medicaid Services issued a provider number to ASPiRA LABS on March 5, 2015.

We terminated our Strategic Alliance Agreement with Quest Diagnostics in August 2013. Prior to the termination, 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

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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 our prior strategic alliance and loan agreements with Quest Diagnostics. We also entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, as amended on April 10, 2015 (the "New Quest Agreement"), Vermillion's wholly-owned subsidiary, ASPiRA LABS, will begin to offer OVA1 testing to Quest Diagnostics customers. We expect Quest Diagnostics to transfer all OVA1 U.S. testing services to ASPiRA LABS, starting with 49 states this year, while continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPiRA LABS for testing for a period of two years from the date of the New Quest Agreement. Pursuant to the agreement, Quest Diagnostics will also continue to offer OVA1 services through its own labs in the remaining state, until ASPiRA LABS has obtained the state approvals required to provide those services. Quest will receive a fee for collection and logistic support services it provides. Per the terms of the New Quest Agreement, we will not offer to existing or future Quest Diagnostics customers CA 125-II or other tests that Quest Diagnostics offers.

On March 27, 2015, we announced initial results from a landmark 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 UC 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.

Study endpoints included treatment costs, quality-adjusted life-years (or QALYs) and incremental cost-effectiveness ratio (called 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. In the model, OVA1 was life-extending and QALY-increasing relative to CA-125 and modified ACOG. OVA1 use in the model resulted in fewer re-operations and pre-treatment CT scans than modified ACOG or CA-125. OVA1 also proved cost effective relative to the $50,000 accepted industry ICER threshold, at about $12,000 per QALY compared to CA125 and $35,000 per QALY versus modified ACOG. These results offer evidence of the value of OVA1 in clinical practice and suggest areas where future clinical utility may be established in future.

On April 14, 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 partnership is focused on retrospective benchmarking of ovarian cancer care study 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 include the future opportunity to collaborate further in identifying a role for innovative diagnostics, such as OVA1 and succeeding second generation

tests, in informing ovarian cancer treatment decisions to better serve patients and optimize the effectiveness of healthcare delivery.

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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.

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Results of Operations - Three Months Ended March 31, 2015 Compared to Three Months Ended March 31, 2014

The selected summary financial and operating data of the Company for the three months ended March 31, 2015 and 2014 were as follows:

(dollars in thousands)	Three Months Ended March 31, 2015	2014	Increase (Decrease) Amount	%
Revenue:				
Product	$ 635	$ 191	$ 444	232
License	316	114	202	177
Total revenue	951	305	646	212
Cost of revenue:				
Product	491	55	436	793
Gross profit	460	250	210	84
Operating expenses:				
Research and development	1,105	1,153	(48)	(4)
Sales and marketing	2,217	2,104	113	5
General and administrative	1,400	988	412	42
Total operating expenses	4,722	4,245	477	11
Loss from operations	(4,262)	(3,995)	(267)	7
Interest income	9	14	(5)	(36)
Other income (expense), net	116	(6)	122	(2,033)
Net loss	$ (4,137)	$ (3,987)	$ (150)	4

Product Revenue. Product revenue was $635,000 for the three months ended March 31, 2015 compared to $191,000 for the same period in 2014. Revenue for the three months ended March 31, 2015 included product revenue of $446,000 related to OVA1 tests performed by Quest Diagnostics. As a result of our March 11, 2015 agreement with Quest Diagnostics, we now realize all product revenue at the time the OVA1 test is performed. During the three months ended March 31, 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 by Quest Diagnostics decreased 7% to approximately 3,567 OVA1 tests during the three months ended March 31, 2015 compared to approximately 3,817 OVA1 tests for the same period in 2014. In addition, ASPiRA LABS performed 216 OVA1 tests during the three months ended March 31, 2015. Total OVA1 tests performed during the three months ended March 31, 2015 were

3,783. Product revenue for the three months ended March 31, 2015 also included the one-time recognition of $163,000 in deferred product revenue upon the signing of the New Quest Agreement on March 11, 2015. We expect product revenue to decrease in the second quarter of 2015 as we transition volume from Quest Diagnostics to ASPiRA LABS. ASPiRA LABS recognizes revenue on the cash basis and thus recognition of revenue lags the performance of an OVA1 test. In addition, we do not expect any one-time revenue items in the second quarter of 2015.

License Revenue. License revenue was $316,000 for the three months ended March 31, 2015 compared to $114,000 for the same period in 2014. Revenue for the three months ended March 31, 2015 included recognition of all remaining deferred license revenue upon the signing of the New Quest Agreement on March 11, 2015 as the period of Quest Diagnostics exclusivity was formally ended. We do not expect to recognize any license revenue in future quarters.

Cost of Revenue. Cost of product revenue was $491,000 for the three months ended March 31, 2015 compared to $55,000 for the same period in 2014. The $436,000 increase is related to the ongoing costs of operating ASPiRA LABS. We expect the cost of revenue to increase significantly 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 March 31, 2015 decreased $48,000, or 4% compared to the same period in 2014. This decrease was primarily due to a decline in costs associated with our collaboration with Johns Hopkins University School of Medicine after we completed the development of OVA2, but was partially offset by $37,000 of internal investment in on-site and off-site R&D activities to fuel our 2015 and 2016 pipeline. 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.

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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 $113,000, or 5%, for the three months ended March 31, 2015 compared to the same period in 2014. The increase was primarily due to expenses incurred as a result of our health economics and outcomes studies in 2015 compared to the same period in 2014.

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 $412,000, or 42%, for the three months ended March 31, 2015 compared to the same period in 2014. The change was due to an increase in personnel costs as we added three core positions, one-time severance expenses, legal expenses, and costs associated with billing for tests performed by ASPiRA Labs.

Other Income (Expense), Net. Other income was $116,000 for the three months ended March 31, 2015 compared to other expense of $6,000 in the same period in 2014. Other income for the three months ended March 31, 2015 related to recognition of one-time items related to the March 11, 2015 agreement with Quest Diagnostics.

Liquidity and Capital Resources

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

We have incurred significant net losses and negative cash flows from operations since inception. At March 31, 2015, we had an accumulated deficit of $355,610,000 and stockholders' equity of $15,190,000. As of March 31, 2015, we had $17,241,000 of cash and cash equivalents and $3,485,000 of current liabilities.

The Company expects cash for OVA tests to be its only material, recurring source of cash in 2015. 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. If the Company is unable to obtain additional capital over the next year, it may be required to delay, reduce the scope of or eliminate key research and development activities, including a planned registry study, which would eliminate or delay our plans to launch future products. This could have a material adverse effect on the Company's business, results of operations and financial condition.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants and dilution to stockholders. If the Company obtains additional funds through arrangements with

collaborators or strategic partners, it may be required to relinquish its rights to certain technologies or products that it might otherwise seek to retain. Additional funding may not be available when needed or on terms acceptable to the Company.

Cash and cash equivalents as of March 31, 2015 and December 31, 2014, were $17,241,000 and $22,965,000 respectively. Working capital was $14,600,000 and $18,739,000 at March 31, 2015 and December 31, 2014 respectively.

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

Net cash used in operating activities was $3,505,000 for the three months ended March 31, 2014 resulting primarily from the net loss reported of $3,987,000 partially offset by changes in assets and liabilities of $435,000.

Net cash used in investing activities of $37,000 and $19,000 for the three months ended March 31, 2015 and 2014, respectively, resulted from purchases of property and equipment.

Net cash used in financing activities for the three months ended March 31, 2015 resulted from the repayment of short-term debt of $1,069,000 and offering expenses incurred of $93,000. Net cash provided by financing activities for the three months ended March 31, 2014 was $11,000, which consists 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 OVA2;

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- 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") credit carryforwards as of March 31, 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 March 31, 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 March 31, 2015. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of March 31, 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.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially and adversely affect our results of operations, cash flows and financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of March 31, 2015, that, in the opinion of management, will have a material adverse effect on our financial position, results of operations or cash flows.

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ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors from those disclosed under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10 K filed with the SEC for the year ended December 31, 2014 (our "2014 Annual Report"). The risks and uncertainties in our 2014 Annual Report are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.

Item 6. Exhibits

(a) The following exhibits are filed or incorporated by reference with this report as indicated below:

Exhibit		Incorporated by Reference				Filed
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	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	Employment Agreement, dated as of April 1, 2015, by and between Vermillion, Inc. and Fred Ferrara #	8-K	001-34810	10.1	April 6, 2015	
10.2	Employment Agreement, dated as of January 7, 2015, by and between Vermillion, Inc. and Laura Miller #	8-K	001-34810	10.1	January 13, 2015	
10.3	Employment Agreement, effective as of January 1, 2015, by and between Vermillion, Inc. and Valerie B. Palmieri #	8-K	001-34810	99.1	December 17, 2015	
10.4	Global Settlement Agreement and Mutual Release, dated as of March 11, 2015, by and between Vermillion, Inc., ASPiRA					X

	LABS, Inc. and Quest Diagnostics Incorporated	
10.5	Testing and Services Agreement, dated as of March 11, 2015, by and between Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated	X
10.6	Amendment No. 1 to the Testing Services Agreement, dated as of March 11, 2015, by and between Vermillion, Inc., ASPiRA LABS, Inc. and Quest Diagnostics Incorporated, dated as of April 10, 2015	X
10.7	Non-Exclusive License Agreement, dated as of March 11, 2015, by and between Quest Diagnostics Clinical Laboratories, Inc., Quest Diagnostics Incorporated, Vermillion, Inc. and ASPiRA LABS, Inc.	X

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31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
31.2	Certification of the Chief Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
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	X
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

Management contracts or compensatory plan or arrangement.

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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: May 11, 2015 /s/ Valerie B. Palmieri
Valerie B. Palmieri

President and Chief Executive Officer

(Principal Executive Officer)

Date: May 11, 2015 /s/ Eric J. Schoen
Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)