VERMILLION, INC.
Form 10-Q
November 14, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

þ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

For the quarterly period ended September 30, 2013.

OR

o 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 þ 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 þ 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 þ

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

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 þ No ¨

As of October 31, 2013, the Registrant had 23,487,927 shares of common stock, par value $0.001 per share, outstanding.

VERMILLION, INC.

FORM 10-Q

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PART I - FINANCIAL INFORMATION

Item 1.Financial Statements

Vermillion, Inc.

Consolidated Balance Sheets

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

(Unaudited)

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 14,604	$ 8,007
Accounts receivable	166	137
Prepaid expenses and other current assets	227	348
Total current assets	14,997	8,492
Property and equipment, net	87	142
Total assets	$ 15,084	$ 8,634
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 422	$ 525
Accrued liabilities	1,485	1,074
Short-term debt	1,106	1,106
Deferred revenue	1,397	492
Total current liabilities	4,410	3,197
Deferred revenue	429	770
Total liabilities	4,839	3,967
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, 2013 and December 31, 2012, respectively	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized at September 30, 2013 and December 31, 2012; 23,487,927 and 15,200,079 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	23	15
Additional paid-in capital	340,669	328,097
Accumulated deficit	(330,447)	(323,445)
Total stockholders' equity	10,245	4,667

Total liabilities and stockholders' equity	$ 15,084	$ 8,634

See accompanying notes to the consolidated financial statements.

Vermillion, Inc.

Consolidated Statements of Operations and Comprehensive Loss

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenue:				
Product	$ 216	$ 205	$ 640	$ 611
License	114	114	341	341
Total revenue	330	319	981	952
Cost of revenue:				
Product	25	33	96	99
Total cost of revenue	25	33	96	99
Gross profit	305	286	885	853
Operating expenses:				
Research and development[1]	553	429	1,591	1,883
Sales and marketing[2]	1,180	1,082	3,172	3,722
General and administrative[3]	889	1,073	3,160	3,381
Total operating expenses	2,622	2,584	7,923	8,986
Loss from operations	(2,317)	(2,298)	(7,038)	(8,133)
Interest income	7	7	15	23
Interest expense	—	(66)	—	(197)
Gain on sale of instrument business	—	50	—	1,830
Gain on litigation settlement, net	—	331	—	710
Reorganization items	—	—	—	88
Other income (expense), net	(4)	(45)	21	(92)
Loss before income taxes	(2,314)	(2,021)	(7,002)	(5,771)
Income tax benefit (expense)	—	—	—	—
Net loss	$ (2,314)	$ (2,021)	$ (7,002)	$ (5,771)
Net loss per share - basic and diluted	$ (0.10)	$ (0.13)	$ (0.36)	$ (0.39)
Weighted average common shares used to compute basic and diluted net loss per common share	23,486,496	15,057,027	19,472,105	14,972,877
Net loss	(2,314)	(2,021)	(7,002)	(5,771)
Foreign currency translation adjustment	—	—	—	(1)
Comprehensive Loss	$ (2,314)	$ (2,021)	$ (7,002)	$ (5,772)
Non-cash stock-based compensation expense included in operating expenses:				
(1) Research and development	$ 12	$ 25	$ 44	$ 99
(2) Sales and marketing	32	55	118	148

(3) General and administrative	22	168	143	552

See accompanying notes to the consolidated financial statements.

Vermillion, Inc.

Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	$ (7,002)	$ (5,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash license revenue	(341)	(341)
Depreciation and amortization	55	64
Loss on sale and disposal of property and equipment	—	3
Stock-based compensation expense	281	789
Warrants issued for services	24	10
Gain from sale of instrument business	—	(1,830)
Changes in operating assets and liabilities:		
Accounts receivable	(29)	(29)
Prepaid expenses and other assets	121	56
Accounts payable, accrued liabilities and other liabilities	308	(1,412)
Deferred revenue	905	523
Reorganization items	—	(32)
Net cash used in operating activities	(5,678)	(7,970)
Cash flows from investing activities:		
Proceeds from the sale of instrument business	—	1,830
Purchase of property and equipment	—	(14)
Net cash provided by investing activities	—	1,816
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	524	6
Net cash provided by financing activities	12,275	6
Effect of exchange rate changes on cash and cash equivalents	—	(1)
Net increase (decrease) in cash and cash equivalents	6,597	(6,149)
Cash and cash equivalents, beginning of period	8,007	22,477
Cash and cash equivalents, end of period	$ 14,604	$ 16,328
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ —	$ 197

See accompanying notes to the 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" and, together with its wholly-owned subsidiaries, "we" or the "Company"), develops and commercializes diagnostic tests in the fields of gynecologic oncology and women's health. In March 2010, we commercially launched the OVA1® ovarian tumor triage test ("OVA1"). We distribute OVA1 through Quest Diagnostics Incorporated ("Quest Diagnostics"), a related party (see Note 3).

Liquidity

On May 13, 2013, we completed a private placement of 8,000,000 shares of our common stock for net proceeds of approximately $11,751,000. We issued warrants to purchase 12,500,000 shares of our common stock in connection with this private placement. If these warrants are exercised, we would realize an additional $18,250,000 of net proceeds.

We expect revenue relating to OVA1 to be our only material, recurring source of cash for the remainder of 2013 and for 2014. Our ability to continue to meet our business objectives in the future is dependent upon, among other things, raising additional capital or generating sufficient revenue in excess of costs. Given these conditions, there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

We may also seek to raise additional capital in the future 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 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 be required to delay, reduce the scope of or eliminate our sales and marketing and/or research and development activities.

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, 2012 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, 2012, included in our Annual Report on Form 10-K which was filed with the Securities and Exchange Commission (the "SEC") on March 1, 2013.

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

We have made no significant changes in our critical accounting policies and significant estimates from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

2. RECENT ACCOUNTING PRONOUNCEMENTS

In February 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") number 2013-02, Other Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income to improve the reporting of reclassifications out of accumulated other comprehensive income. ASU 2013-02 requires reporting the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. It is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2012. The adoption of this ASU does not affect the accompanying interim consolidated financial statements, but could require additional disclosure, if applicable, in future periods.

In July 2013, the FASB issued ASU number 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists — a consensus of the FASB Emerging Issues Task Force. ASU 2013-11 generally requires, with some exceptions, an entity to present its unrecognized tax benefits as it relates to its net operating loss carryforwards, similar tax losses, or tax credit carryforwards, as a reduction of deferred tax assets when settlement in this regard is available under the tax law of the applicable taxing jurisdiction as of the balance sheet reporting date. It is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. Retrospective application is permitted. We do not anticipate a material impact on our financial position, results of operations or cash flows as a result of this change.

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

On July 22, 2005, we entered into a Strategic Alliance Agreement (as amended, the "Strategic Alliance Agreement") with Quest Diagnostics Incorporated ("Quest Diagnostics") to develop and commercialize up to three diagnostic tests from our product pipeline. In connection with the Strategic Alliance Agreement, we entered into a Credit Agreement with Quest Diagnostics, pursuant to which Quest Diagnostics provided us 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 our intellectual property assets. Pursuant to the Strategic Alliance Agreement, Quest Diagnostics selected two diagnostic tests to be commercialized, a peripheral arterial disease diagnostic test (differentiated from our ongoing program) 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 on October 7, 2012.

We believe that, in September 2009, when the United States Food and Drug Administration (the "FDA") cleared our application for a licensed laboratory test of OVA1 to be commercialized, we 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, we 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 we believed that, following this reduction, the principal balance under the line of credit was $6,000,000, we 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.

On October 12, 2012, we paid Quest Diagnostics approximately $5,894,000 of principal which we believe represented payment in full of all then outstanding principal under the secured line of credit. However, we continue to show the amount of the liability as $1,106,000 as of September 30, 2013 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, on May 23, 2013, we 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. Quest Diagnostics has disputed the effectiveness of our notice of default. On August 23, 2013, we sent Quest Diagnostics a notice of termination. Notwithstanding the termination, we 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 lab 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 our notice of termination.

4. COMMITMENT AND CONTINGENCIES

We lease a facility located in Austin, Texas with an annual base rent of $57,000 and annual estimated common area charges, taxes and insurance of $37,000. This lease expires on May 31, 2014.

Contingent Liabilities

Robert Goggin and György Bessenyei Litigation

On May 25, 2012, György B. Bessenyei and Robert S. Goggin, III, both stockholders of Vermillion and Mr. Goggin a Director of Vermillion since March 21, 2013, filed a verified complaint in the Delaware Court of Chancery (the "Court") against Vermillion, each member of our Board of Directors at the time, and Gail S. Page, our former Chairman of the Board and Chief Executive Officer. The complaint was subsequently amended. As amended, the complaint alleged that the Board of Directors and Ms. Page had breached their fiduciary duties by amending our bylaws to eliminate a seat on our Board of Directors formerly held by Ms. Page and that the Board of Directors' actions were intended both to prevent Mr. Bessenyei's and Mr. Goggin's nominees from being able to be elected to the Board of Directors, and to entrench the Board of Directors' current members.

On November 16, 2012, the Court dismissed the lawsuit with prejudice. The plaintiffs filed a notice of appeal of that dismissal order on December 10, 2012, and argument was held on May 22, 2013. On May 24, 2013, the Delaware Supreme Court issued an order affirming the Court's dismissal of the lawsuit with prejudice. As a result of this order, there is no longer any pending litigation between Vermillion and Mr. Bessenyei or Mr. Goggin.

In addition, from time to time, we are involved in legal proceedings and regulatory proceedings arising in the ordinary course of conducting our business. We establish reserves for specific liabilities that we deem to be probable and estimable. We are not currently a party to any proceeding, the adverse outcome of which would reasonably be expected to have a material adverse effect on our financial position or results of operations.

5. STOCKHOLDERS' EQUITY

Stock Purchase

On May 13, 2013, we completed a private placement pursuant to which existing and new investors purchased 8,000,000 shares of our common stock at a price per share of $1.46. We also issued warrants to purchase shares of our common stock at a price per warrant share of $0.125 in the private placement. The proceeds of the private placement were $13,242,500 (net proceeds of approximately $11,751,000 after deducting offering expenses). The warrants are exercisable for 12,500,000 shares of common stock at $1.46 per share and expire on May 13, 2016.

The purchase of common stock and warrants qualified for equity treatment under GAAP. The respective values of the warrants and common stock were calculated using their relative fair values and classified under common stock and additional paid in capital. The value ascribed to the warrants is $9,300,000 and for the common stock is $3,943,000.

In connection with the private placement, the Company entered into a Stockholders Agreement with the purchasers named in that agreement. Pursuant to, and subject to the terms of, the Stockholders Agreement, certain of the investors received rights to participate in any future equity offerings on the same price and terms as other investors. In addition, the Stockholders Agreement prohibits the Company from taking material actions without the consent of at least one of the two primary investors. These material actions include:

· Making any acquisition with value greater than $2 million;

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Entering into, or amending the terms of agreements with Quest Diagnostics, provided that such investors' consent shall not be unreasonably withheld, conditioned or delayed following good faith consultation with the Company;

· Submitting any resolution at a meeting of stockholders or in any other manner changing or authorizing a change in the size of the Board of Directors;

· Offering, selling or issuing any securities senior to Vermillion's common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to Vermillion's common stock;

· Amending Vermillion's certificate of incorporation or by-laws in any manner that affects the rights, privileges or economics of Vermillion's common stock or the warrants described above;

· Taking any action that would result in a change in control of Vermillion or an insolvency event;

· Paying or declaring dividends on any securities of the Company or distributing any assets of the Company other than in the ordinary course of business or repurchasing any outstanding securities of the Company; or

· Adopting or amending any shareholder rights plan.

In addition, the two primary investors each received the right to designate a person to serve on our Board of Directors. These rights terminate for each stockholder when that stockholder ceases to beneficially own less than 50% of the shares and warrants (taking into account shares issued upon exercise of the warrants), in the aggregate, than were purchased at the closing of the private placement.

Stock Option Exercises

During the nine months ended September 30, 2013, options to purchase 271,348 shares of Vermillion common stock were exercised for total proceeds to Vermillion of $524,000.

2010 Stock Incentive Plan

The Company's employees, directors, and consultants are eligible to receive awards under our 2010 Stock Incentive Plan (the "2010 Plan"). There were approximately 75,000 shares available for grant under the 2010 Plan at September 30, 2013.

Employee Stock-Based Compensation

On March 18, 2013, we granted 400,000 stock options with an exercise price of $1.22 per share to our President and Chief Executive Officer and on May 28, 2013, we granted 242,500 stock options with an exercise price of $3.37 per share to certain other officers and employees. These grants were made pursuant to the 2010 Plan and are subject to approval by our stockholders of an increase in the number of shares authorized under our 2010 Plan. The stock options vest in 48 equal monthly installments. Pursuant to Accounting Standards Codification 718, "Compensation – Stock Compensation," there is no stock-based compensation expense recognized for these stock option grants until approval by our stockholders of an increase in the number of shares authorized under our 2010 Stock Incentive Plan.

The allocation of employee stock-based compensation expense by functional area for the three and nine months ended September 30, 2013 and 2012 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2013	2012	2013	2012
Research and development	$ 12	$ 23	$ 42	$ 86
Sales and marketing	32	55	118	148
General and administrative	9	165	119	534
Total	$ 53	$ 243	$ 279	$ 768

6. LOSS PER SHARE

We calculate basic loss per share using the weighted average number of common shares outstanding during the period. Because we are 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 13,330,302 and 1,167,109 potential common shares as of September 30, 2013 and 2012, 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

Quest Diagnostics is a stockholder and was the holder of our secured line of credit (see Note 3). Accounts receivable from Quest Diagnostics under the Strategic Alliance Agreement totaled $166,000 and $137,000 at September 30, 2013 and December 31, 2012, respectively.

Consulting Agreement

In June 2011, we entered into a consulting agreement with Bruce A. Huebner, a member of our Board of Directors. Pursuant to the terms of the consulting agreement, Mr. Huebner provided consulting services regarding sales, marketing, business development and corporate strategy. For the year ended December 31, 2012, the total amount of consulting fee expense for Mr. Huebner was $5,000. On November 27, 2012, we announced the appointment of Mr. Huebner as Interim Chief Executive Officer. Mr. Huebner served in this position until the appointment of Thomas McLain as President and Chief Executive officer on March 18, 2013.

On March 18, 2013, we entered into a short term consulting agreement for transition services with Mr. Huebner (the “2013 Consulting Agreement”). Pursuant to the terms of the 2013 Consulting Agreement, Mr. Huebner assisted in the integration and transition of our new President and Chief Executive Officer. Mr. Huebner was paid $15,000 per month during the three month term of the Consulting Agreement, which expired in June 2013. Mr. Huebner was elected as Chairman of the Board of Directors, also on March 18, 2013.

Stockholders Agreement

On May 13, 2013, we completed a private placement pursuant to which existing and new investors purchased 8,000,000 shares of our common stock and warrants to purchase 12,500,000 shares of our common stock. We entered into a Stockholders Agreement with the purchasers in the private placement. See Note 5 for a description of certain terms of the Stockholders Agreement.

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

Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," 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 occurring after such date. Examples of language found in forward-looking statements include the following:

- projections of our future revenue, results of operations and financial condition;
- anticipated efficacy of our products, product development activities and product innovations;
- our ability to consolidate the five OVA1 immunoassays on a single mainstream integrated diagnostic automation platform;
- competition and consolidation in the markets in which we compete;
- existing and future collaborations and partnerships;
- the utility of biomarker discoveries;
- 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 ability to comply with applicable government regulations;
- our 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;
- results of clinical trials, post-market studies required by FDA, and publications on OVA1;
- resolution of any outstanding amount under the secured line of credit with Quest Diagnostics;
- commercialization of tests through and recognition of revenue under our agreement with Quest Diagnostics;
- the ability to expand the market to other clinical laboratories in addition to Quest Diagnostics;
- the amount of financing required to fund our planned operations;
- the potential loss of expected funding in the event that the warrants issued by us on May 13, 2013 are not exercised;
- 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
- the consolidation of holdings of our common stock in the hands of fewer investors; 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.

Such statements are subject to significant risks and uncertainties, including those identified under in Part II, Item 1A of our Quarterly Report on Form 10-Q for the three months ended March 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 generate sales after completing development of diagnostic products; our ability to manage our operating expenses and cash resources consistently with our plans; our ability to secure adequate funds on acceptable terms to execute our business plan; our ability to develop and commercialize diagnostic products using both our internal and external research and development resources; our ability to obtain market acceptance of OVA1 or future diagnostic products, including the risk that our products will not be competitive with products offered by other companies, or that our products may not receive support from various professional and medical societies, or that users will not be entitled to receive adequate reimbursement for our products from third party payers such as private insurance companies and

government insurance plans; our ability to successfully license or otherwise successfully partner with third parties to commercialize our products; our ability to obtain any regulatory approval for our future diagnostic products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; our success in achieving development milestones, achieving desired results in clinical trials or

FDA-mandated studies; and our ability to protect and promote our proprietary technologies. 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 become a recognized leader in the advancement of women's health by providing innovative methods that detect, monitor and manage the treatment of gynecologic cancers.

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 tests are intended to detect, diagnose and stage disease, and to help guide decisions regarding prognosis and patient treatment. These may include decisions to refer patients to specialists, to perform additional testing, or to assist in the selection or monitoring of therapy and disease progression. A distinctive feature of our approach is to combine multiple biomarkers into a single, reportable index score that has higher diagnostic effectiveness than its constituents.

We concentrate our development of novel diagnostic tests in the fields of gynecologic oncology and women's health, with the 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 other issues in the fields of oncology and women's health through collaborations with leading academic and clinical research institutions.

Our lead product, OVA1, an ovarian cancer blood test, was cleared by the United States Food and Drug Administration ("FDA") in September 2009.

We are focused on the execution of three core strategic business drivers to build long term value for our investors:

- Maximizing the existing OVA1 opportunity by taking the leadership role in expanding commercialization, payer coverage and inclusion in guidelines

- Expanding our customer base by migrating OVA1 to a platform available globally

- Expanding our patient base by launching a next generation ovarian cancer test to monitor at risk patients

We believe that these business drivers are critical elements in the continued development of our business.

OVA1 addresses a clear unmet 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 FDA-cleared software to determine the likelihood of malignancy in women over age 18 with a pelvic mass for whom surgery is planned. OVA1 was developed through large 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. This work was published in two articles in the journal Obstetrics & Gynecology (also known as the Green Journal). The results of the pivotal study

demonstrated that in a cohort of 516 patients, OVA1, in conjunction with clinical evaluation, was able to identify 95.7% (154/161) of the malignant ovarian tumors overall, and to rule out malignancy with a negative predictive value ("NPV") of 94.6% (123/130). At the 2010 International Gynecologic Cancer Society Meeting, data were presented demonstrating the high sensitivity of OVA1 for epithelial ovarian cancers; OVA1 detected 95/96 epithelial ovarian cancer cases for a sensitivity of 99.0%, including 40/41 stage I and stage II epithelial ovarian cancers, for an overall sensitivity of 97.6% for early stage epithelial ovarian cancers, as compared to 65.9% for CA125 using the American College of Obstetricians and Gynecologists ("ACOG") cutoffs. The improvement in sensitivity was even greater among premenopausal women; for OVA1, sensitivity for early stage epithelial ovarian cancer was 92.9% and for CA125, sensitivity was 35.7%. Overall, OVA1 detected 76% of malignancies missed by CA125, including all advanced stage malignancies. OVA1 is not indicated for use as a screening or stand-alone diagnostic assay.

The American Medical Association (AMA) Current Procedural Terminology (CPT®) Panel approved a Category I CPT code (81503) for OVA1, which became effective January 1, 2013.

In 2012, we completed a second pivotal clinical study of OVA1, called the "OVA500 study" and led by Dr. Robert E. Bristow, Director of Gynecologic Oncology Services with UC Irvine Healthcare. The study evaluated OVA1 performance in a population of 494 patients who underwent surgery for an adnexal mass after enrollment by a non-gynecologic oncologist, the intended use population for routine OVA1 testing. In the new study, of the 27 sites used in each study, only 10 were common to both. Collectively, the clinical trial and the OVA500 study evaluated 1,110 eligible subjects at a total of 44 sites. Despite the difference in population between the two studies, and the large number of differing sites, the sensitivity of OVA1 added to clinical impression (also called OVA1 dual assessment) was identical, at 95.7% (88/92). In addition, overall NPV of OVA1 dual assessment was 98.1% (204/208), higher than the 94.6% NPV found in the earlier validation study. In premenopausal surgery patients, OVA1 dual assessment sensitivity was 93.5% (29/31), NPV was 98.6% (145/147) and specificity was 58.9% (145/246) when combined with clinical assessment. OVA1 also showed strong performance in detecting early stage malignancies. OVA1 correctly stratified 91.4% (32/35) of early stage cancers and 89.3% (25/28) of stage I cancers as high risk, respectively. In comparison, CA125-II sensitivity was

65.7% (23/35) for early stage and 64.3% (18/28) for stage I malignancies. Overall, the results strongly and independently confirmed the clinical performance of OVA1 in presurgical triage of adnexal mass patients, including premenopausal and early stage cancers.

The OVA500 study was published in February 2013 in the peer-reviewed journal Gynecologic Oncology, which enjoys the highest impact factor rating of any journal worldwide focused on gynecologic oncology. The results have also been incorporated into an updated medical education presentation, as well as our marketing and reimbursement collateral. 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.

Dr. Bristow presented another study at the Society of Gynecological Oncology (“SGO”) in March 2013 which was published in the Green Journal in June 2013. It 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 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 25 percent of those whose care fell short.

This study was featured on the front page of the New York Times under the headline, "Widespread Flaws Found in Ovarian Cancer Treatment." According to Dr. Bristow, principal investigator of the study, “If we could just make sure that women get to the people who are trained to take care of them, the impact would be much greater than that of any new chemotherapy drug or biological agent.” (NY Times, March 11, 2013, Denise Grady)

On April 17, 2013, we announced the signing of a cooperative research and development agreement (CRADA) with the U.S. Army Medical Research and Materiel Command (USAMRMC). The agreement marks the launch of a project titled, "Cost Reduction Using OVA1 in a Treatment Algorithm for Adnexal Masses in Women," and follows the January 2012 decision by the U.S. Department of Defense to add OVA1 to its testing portfolio. The two-phase study will investigate the cost-benefit profile of OVA1 testing as a presurgical standard of care in women with pelvic masses, and assess OVA1 clinical utility in a managed care setting.

Phase 1 will retrospectively assess medical outcomes and total cost of care to establish historical benchmarks and estimate potential benefits of OVA1 utilization. Phase 2 will involve a multi-center prospective clinical study within the Western Regional Command to assess OVA1 as a standard of care across a large sector of the U.S. Armed Forces. We believe the project will further support our reimbursement efforts, by gathering data on the real-world impact of OVA1 on medical and health economic outcomes compared with accurate and holistic benchmarks.

On May 6, 2013, we received notification that platform support for one of the five immunoassay component kits that are used in OVA1 is to be discontinued effective December 2014. As part of our existing strategic product roadmap, we had planned on consolidating the five OVA1 immunoassays on a single mainstream integrated diagnostic automation platform, and as part of the consolidation we expect to validate a new immunoassay method to replace the discontinued method. We are required to submit these changes pursuant to a 510k submission with the FDA. We consider consolidating the immunoassay components on a single platform to be a strategic step toward allowing OVA1 broader market access, including potential commercialization outside the United States. As of the date of filing

this quarterly report on Form 10Q, we anticipate this project will be completed without material business interruption. However, no assurances can be made that the FDA will clear our expected 510(k) submission.

In June 2013, OVA1 received a new position statement on OVA1 use issued by the SGO. 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."

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 new statement does two things:

- Refers to 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.

In another program, we have completed “proof of concept” work which was intended to identify markers with high clinical specificity that may complement OVA1. Preliminary results were presented on June 3, 2013, in a poster at the annual meeting of the American Society for Clinical Oncology (ASCO) by Dr. Zhen Zhang (Johns Hopkins University) and co-workers. The studies identified a set of 5 biomarkers (CA125, prealbumin, IGFBP2, IL6, and FSH) which optimally reduced false positives among a targeted set of OVA1-positive benign patients. This panel was subsequently tested in a 50/50 cross-validation strategy against a sampling of OVA500 patients (N=384), to evaluate specificity and other diagnostic parameters. At a fixed sensitivity of 90%, the median specificity of models using the new panel in testing was 80.6%. The mean and median absolute improvements over that of OVA1 were 18.6% and 20.3%, respectively. The new panel demonstrated the possibility to improve specificity over that of the existing OVA1 algorithm, while maintaining a high sensitivity in pre-surgical assessment of adnexal masses for risk of malignancy. The work has been submitted to a peer-reviewed journal for publication later this year or early in 2014.

These experiments are early stage and preliminary in nature as they have not yet been submitted for publication in a peer-reviewed journal, though submission is expected within the next two quarters. Any actual product development, if pursued, will likely differ significantly depending on a number of technical and commercial factors. We have yet to identify one or more intended uses, or establish a regulatory or commercial pathway for a potential next-generation OVA product utilizing this or another new panel.

On November 12, 2013, we announced that a new study of OVA1 clinical performance in the presurgical detection of ovarian cancer, entitled “Clinical Performance of a Multivariate Index Assay For Detecting Early-Stage Ovarian Cancer” was published in The American Journal of Obstetrics & Gynecology. Co-authored by Dr. Robert E. Bristow (UC Irvine Healthcare) and Dr. Frederick R. Ueland (U. Kentucky), the new analysis focused on presurgical detection of early-stage ovarian cancer among 1,016 ovarian mass surgery patients in two previous pivotal trials conducted in 2007 and 2012. The study compared OVA1 performance in early-stage ovarian cancer to commonly used cancer risk assessment protocols: overall clinical assessment, the CA125 biomarker or modified-American College of Obstetricians and Gynecologists (mod-ACOG) guidelines for evaluation of suspicious pelvic masses. The findings were previously presented at the Annual Meeting of the Western Association of Gynecologic Oncologists in Seattle in June 2013.

In a statement regarding this new study, Dr. Bristow stated, “Early-stage ovarian cancer constitutes an important opportunity to improve survival and care for this most deadly gynecologic cancer. However, as evidenced by recent studies, most ovarian cancer patients fail to be referred to the doctors and hospitals best equipped to treat them, resulting in unfortunate consequences. Our new study demonstrates OVA1’s ability to detect the majority of all early-stage ovarian cancers prior to surgery and thereby aid in appropriately involving a gynecologic oncologist in their care. Even among premenopausal patients where primary ovarian cancer prevalence was just 15%, clinical assessment with OVA1 detected stage I ovarian cancer with almost 90% sensitivity. This is a very encouraging development for the diagnosis and treatment of ovarian cancer.”

Also on November 12, 2013, we announced that a new clinical study published in The American Journal of Obstetrics & Gynecology has reported superior sensitivity of OVA1 for presurgical triage of ovarian cancer, compared with commonly used risk assessment methods. The new study compared OVA1 performance to benchmark triage methods, within a combined cohort of 770 ovarian mass surgery patients (including 164 malignancies) from two independent but related OVA1 pivotal trials conducted in 2007 and 2012. The study also compared the actual rate of patient referral from non-specialist physicians to gynecologic oncologists (GO's) with rates predicted from clinical assessment, OVA1, CA125 or from the modified-American College of Obstetricians and Gynecologists (mod-ACOG) guidelines. We also reported the findings on the same day at the AAGL (or American Association of Gynecologic Laparoscopists) "42nd Global Congress of Minimally Invasive Gynecology."

Current and former academic and research institutions that we have or have had collaborations with include the Johns Hopkins University School of Medicine; the University of Texas M.D. Anderson Cancer Center; University College London; the University of Texas Medical Branch; the Katholieke Universiteit Leuven; Clinic of Gynecology and Clinic of Oncology, Rigshospitalet, Copenhagen University Hospital; The Ohio State University Office of Sponsored Programs; Stanford University; the University of Kentucky, and the University of California at Irvine.

In October 2013, we amended our existing collaboration agreement with the Johns Hopkins University School of Medicine, and we agreed to pay approximately $1.6 million through June 2015 for assistance with (1) the migration of the existing OVA1 test to a new platform and (2) the development, submission and launch of a next-generation ovarian cancer diagnostic.

Novitas Solutions (formerly Highmark Medicare Services), a Medicare contractor, covers and reimburses for OVA1.

We received favorable coverage decisions from 28 Blue Cross Blue Shield ("BCBS") plans following the launch of OVA1. This was based in part on reviews from the BCBS Association's Medical Policy Panel in 2010 and 2011. However, in April 2013, the

BCBS Technical Evaluation Center ("TEC") classified OVA1 as experimental/investigational and thus it did not meet the TEC's criteria for coverage. Based on that assessment, 14 BCBS plans have reversed their coverage decisions for OVA1or announced an intention to do so, adversely impacting our number of covered lives. Two additional plans have recently retired their coverage decisions meaning that claims going forward will be evaluated on a case by case basis.

We believe the TEC assessment classifying OVA1 as experimental/investigational is flawed and rebuttable on multiple points. Most notably, the TEC assessment was conducted during 2012 and did not consider the OVA500 study published in February 2013, the updated Society for Gynecological Oncology statement on the use of OVA1 issued in May 2013 and the June 2013 publication of a comprehensive study on widespread flaws in the care of women with ovarian cancer that can be addressed in large part with the use of diagnostics such as OVA1.

We are actively undertaking an effort to address the TEC assessment with BCBS plans that still maintain favorable coverage decisions and those that have reversed coverage decisions. We are providing the peer reviewed studies that have been published since 2012 and we also plan to request that TEC rescind the April 2013 decision on OVA1. When Quest Diagnostics provides us with information, we are also actively appealing decisions where coverage for OVA1 is denied. We believe our cumulative efforts to increase test volumes will more than offset any negative impact from the TEC assessment. However, there can be no guarantee that we will be successful in our appeals of coverage decisions or our rescission request, or that if we are successful, it will have a positive impact on the level of reimbursement or our revenue.

There are currently 12 independent BlueCross BlueShield plans, representing approximately 19.1 million lives, which provide coverage for OVA1. In total, including Medicare and other private payers, approximately 65.6 million patients have access and coverage for OVA1.

In January 2012, the Department of Defense added OVA1 to their Quest Diagnostics lab services contract, giving more than 45 military medical centers in the U.S. and numerous military medical clinics and facilities around the world access to OVA1 for the first time. In 2013, a smaller non-multi-year contract modification for laboratory testing services for all military members and dependents was awarded Sept 6, 2013 to Quest Diagnostics (contract # W81K04-12-D-0013) by The U.S. Army Medical Command - Contracting Center, Fort Sam Houston, Texas. As a result, uniformed military service members still have access to OVA1. Approximately 1.4 million uniformed service members have access to OVA1 through the Department of Defense, bringing the covered lives total to an estimated 67.0 million.

Under the terms of our Strategic Alliance Agreement with Quest Diagnostics, which we terminated on August 23, 2013, Quest Diagnostics was required to pay us a fixed payment of $50 per OVA1 performed, as well as 33% of its "gross margin" from revenue from performing OVA1 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 in its exclusive territory, which includes the US, Mexico, the United Kingdom and India through September 11, 2014. Quest Diagnostics had the right to extend its exclusivity period for an additional year beyond September 11, 2014 on the same terms and conditions. On May 23, 2013, we sent Quest Diagnostics a notice of default under the Strategic Alliance Agreement relating to a number of 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. Quest Diagnostics has disputed the effectiveness of our notice of default. On August 23, 2013, we sent Quest Diagnostics a notice of termination. Notwithstanding the termination, we agreed that Quest 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. Quest Diagnostics has disputed the effectiveness of our notice of termination.

Critical Accounting Policies and Significant Estimates

There have been no material changes to our critical accounting policies and significant estimates as disclosed in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

Results of Operations - Three Months Ended September 30, 2013 Compared to Three Months Ended September 30, 2012

The selected summary financial and operating data of Vermillion for the three months ended September 30, 2013 and 2012 were as follows:

(dollars in thousands)	Three Months Ended September 30, 2013	2012	Increase (Decrease) Amount	%
Revenue:				
Product	$ 216	$ 205	$ 11	5
License	114	114	—	—
Total revenue	330	319	11	3
Cost of revenue:				
Product	25	33	(8)	(24)
Total cost of revenue	25	33	(8)	(24)
Gross profit	305	286	19	7
Operating expenses:				
Research and development	553	429	124	29
Sales and marketing	1,180	1,082	98	9
General and administrative	889	1,073	(184)	(17)
Total operating expenses	2,622	2,584	38	1
Loss from operations	(2,317)	(2,298)	(19)	1
Interest income	7	7	-	-
Interest expense	—	(66)	66	—
Gain on sale of instrument business	—	50	(50)	—
Gain on litigation settlement, net	—	331	(331)	—
Other expense, net	(4)	(45)	41	(91)
Loss before income taxes	(2,314)	(2,021)	(293)	14
Income tax benefit (expense)	—	—	—	—
Net loss	$ (2,314)	$ (2,021)	$ (293)	14

Product Revenue. Product revenue was $216,000 for the three months ended September 30, 2013 compared to $205,000 for the same period in 2012. We recognized product revenue for the three months ended September 30, 2013 for the sale of OVA1 through Quest Diagnostics. The number of OVA1 tests performed by Quest Diagnostics increased 6% from approximately 4,100 OVA1 tests during the three months ended September 30, 2012 to approximately 4,328 OVA1 tests for the same period in 2013. Product revenue increased for the three months ended September 30, 2013 compared to the same period in 2012 due to the increased volume of tests. Product revenue for the three months ended September 30, 2013 was substantially derived from domestic sales of OVA1.

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, 2013 increased $124,000, or 29% compared to the same period in 2012. This increase was due primarily to increased expenses of our post-marketing study in 2013. We expect research and development expense to increase in future periods as we continue to invest in our product pipeline and progress our migration to a new testing platform and continue our FDA-required post-marketing study to verify the performance characteristics of OVA1 in routine clinical use.

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 $98,000, or 9%, for the three months ended September 30, 2013 compared to the same period in 2012. The change was due primarily to an increase in personnel and personnel-related costs due to higher headcount. We expect sales and marketing expenses to increase in future periods as we have recently added headcount to our reimbursement team as well our sales team.

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 decreased by $184,000, or 17%, for the three months ended September 30, 2013 compared to the same period in 2012. The change was due to a decrease in legal fees as costs incurred in the prior year for the Goggin/Bessenyei litigation and proxy contest were not repeated in 2013. This decrease was partially offset by an increase in patent-related legal costs in the three months ended September 30, 2013 compared to the same period in 2012.

Interest Expense. Interest expense decreased to $0 due to the payoff of the Quest Diagnostics loan in October 2012.

Gain on Litigation Settlement, Net. On February 9, 2012, we entered into a Settlement Agreement with Oppenheimer & Co., Inc. related to losses on our short and long-term investments in previous years. Under the terms of the Settlement Agreement, the total settlement payable to the Company was $1,000,000; of which $535,000 ($379,000 net after legal fees and costs) was paid in March 2012 and $465,000 ($331,000 net after legal fees and costs) was paid on September 1, 2012. The gain on litigation settlement represents the net proceeds received from the September 2012 payment.

Results of Operations - Nine Months Ended September 30, 2013 Compared to Nine Months Ended September 30, 2012

The selected summary financial and operating data of Vermillion for the nine months ended September 30, 2013 and 2012 were as follows:

	Nine Months Ended September 30,		Increase (Decrease)	
(dollars in thousands)	2013	2012	Amount	%
Revenue:				
Product	$ 640	$ 611	$ 29	5
License	341	341	—	—
Total revenue	981	952	29	3
Cost of revenue:				
Product	96	99	(3)	(3)
Total cost of revenue	96	99	(3)	(3)
Gross profit	885	853	32	4
Operating expenses:				
Research and development	1,591	1,883	(292)	(16)
Sales and marketing	3,172	3,722	(550)	(15)
General and administrative	3,160	3,381	(221)	(7)
Total operating expenses	7,923	8,986	(1,063)	(12)
Loss from operations	(7,038)	(8,133)	1,095	(13)
Interest income	15	23	(8)	(35)
Interest expense	—	(197)	197	—
Gain on sale of instrument business	—	1,830	(1,830)	—
Gain on litigation settlement, net	—	710	(710)	—
Reorganization items	—	88	(88)	—
Other income (expense), net	21	(92)	113	(123)
Loss before income taxes	(7,002)	(5,771)	(1,231)	21
Income tax benefit (expense)	—	—	—	—
Net loss	$ (7,002)	$ (5,771)	$ (1,231)	21

Product Revenue. Product revenue was $640,000 for the nine months ended September 30, 2013 compared to $611,000 for the same period in 2012. We recognized product revenue for the nine months ended September 30, 2013 for the sale of OVA1 through Quest Diagnostics. Quest Diagnostics performed approximately 12,786 OVA1 tests during the nine months ended September 30, 2013 compared to approximately 12,202 tests for the same period in

2012. Product revenue increased for the nine months ended September 30, 2013 compared to the same period in 2012 due to the increased volume of tests. Product revenue for the nine months ended September 30, 2013 was substantially derived from domestic sales of OVA1.

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 decreased by $292,000, or 16%, for the nine months ended September 30, 2013 compared to the same period in 2012. This decrease was due primarily to expenses for the start-up costs of our post-marketing study in 2012 that were not repeated in 2013. In addition, personnel related costs were lower in 2013 due to lower headcount compared to 2012. We expect research and development expense to increase in future periods as we continue to invest in our product pipeline and progress our migration to a new testing platform and continue our FDA-required post-marketing study to verify the performance characteristics of OVA1 in routine clinical use.

Sales and Marketing Expenses. Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and health economic publications. Sales and marketing expenses decreased by $550,000, or 15%, for the nine months ended September 30, 2013 compared to the same period in 2012. The change was due primarily to certain consulting expenses in 2012 that was not repeated in 2013 as well

as a decrease in personnel and personnel-related costs due to lower headcount. In addition, advertising and trade show costs decreased due to lower advertising and trade show activity. We expect sales and marketing expenses to increase in future periods as we have recently added headcount to our reimbursement team as well our sales team.

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 decreased by $221,000, or 7%, for the nine months ended September 30, 2013 compared to the same period in 2012. The decrease was due primarily to lower legal expenses in 2013 as we currently have no litigation pending against the company.

Interest expense. Interest expense decreased to $0 due to the payoff of the Quest Diagnostics loan in October 2012.

Gain on sale of instrument business. Gain on sale of instrument business was $1,830,000 for the nine months ended September 30, 2012. This gain resulted from the return in 2012 of funds held in escrow from our 2006 sale of the instrument business to Bio-Rad.

Gain on litigation settlement, net. On February 9, 2012, we entered into a Settlement Agreement with Oppenheimer & Co., Inc. related to losses on our short and long-term investments in previous years. Under the terms of the Settlement Agreement, the total settlement payable to the Company was $1,000,000; of which $535,000 ($379,000 net after legal fees and costs) was paid in March 2012 and $465,000 ($331,000 net after legal fees and costs) was paid on September 1, 2012. The gain on litigation settlement represents recognition of the net proceeds received.

Liquidity and Capital Resources

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

We have incurred significant net losses and negative cash flows from operations since inception. At September 30, 2013, we had an accumulated deficit of $330,447,000 and stockholders' equity of $10,245,000. As of September 30, 2013, we had $14,604,000 of cash and cash equivalents and $4,410,000 of current liabilities.

On May 13, 2013, we completed a private placement of 8,000,000 shares of our common stock for estimated net proceeds of approximately $11,751,000. We issued warrants to purchase 12,500,000 shares of our common stock in connection with this private placement. If these warrants are exercised, we would realize an additional $18,250,000 of net proceeds.

We expect revenue relating to OVA1 to be our only material, recurring source of cash for the remainder of 2013 and for 2014. Our ability to continue to meet our business objectives in the future is dependent upon, among other things, raising additional capital or generating sufficient revenue in excess of costs. Given these conditions, there is substantial doubt about the Company's ability to continue as a going concern. The interim consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

We may also seek to raise additional capital in the future 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. 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 be required to delay, reduce the scope of or eliminate our sales and marketing and/or research and development activities.

Cash and cash equivalents as of September 30, 2013 and December 31, 2012, were $14,604,000 and $8,007,000, respectively. Working capital was $10,587,000 and $5,295,000 at September 30, 2013 and December 31, 2012, respectively.

Net cash used in operating activities was $5,678,000 for the nine months ended September 30, 2013 compared to $7,970,000 for the nine months ended September 30, 2012. The decrease in net cash used in operating activities resulted primarily from an increase in cash provided by changes in operating assets and liabilities from $894,000 for the nine months ended September 30, 2012, to $1,305,000 for the comparable period in 2013. Cash provided by changes in operating assets and liabilities for the nine months ended September 30, 2013 was mainly driven by a $905,000 increase in deferred revenue and a $308,000 increase of accounts payable, accrued liabilities and other liabilities. A decrease in stock-based compensation expense, which was $281,000 for the nine months ended September 30, 2013, compared to $789,000 for the comparable period in 2012, also contributed to the decrease in net cash used in operating activities.

There was no net cash used in investing activities for the nine months ended September 30, 2013. Net cash provided by investing activities for the nine months ended September 30, 2012 was $1,816,000 due primarily to the receipt of escrow funds upon completion of the 2006 sale of instrument business to Bio-Rad.

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

Net cash provided by financing activities was $6,000 for the nine months ended September 30, 2012, which resulted from net proceeds from issuance of common stock from exercise of stock options.

Our future liquidity and capital requirements will depend upon many factors, including, among others:

- resources devoted to establish sales, marketing and distribution capabilities;
- the rate of product adoption by physicians and patients;
- our determination to acquire or invest in other products, technologies and businesses;
- the market price of our common stock as it affects the exercise of stock options; and
- the insurance payer community's acceptance of and reimbursement for OVA1.

We have significant net operating loss ("NOL") credit carryforwards as of September 30, 2013 for which a full valuation allowance has been provided due to our history of operating losses. Our ability to use our net NOL credit carryforwards may be restricted due to ownership change limitations occurring in the past or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. These ownership changes may also limit the amount of NOL credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

Off-Balance Sheet Arrangements

As of September 30, 2013, 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 Vice President, Finance 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, 2013. Based on this evaluation, our Chief Executive Officer and Vice President, Finance and Chief Accounting Officer have concluded that as of September 30, 2013, 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 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, 2013, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

There have been no material changes to our risk factors from those disclosed under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2012, except as set forth in Part II, Item 1A of our Quarterly Report on Form 10-Q for the three months ended March 31, 2013.

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	Fourth Amended and Restated Bylaws of Vermillion, Inc., effective May 13, 2013	8-K	001-34810	3.2	May 14, 2013	
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					ü
31.2	Certification of the Chief Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					ü
32.1	Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					(1)
101.INS	XBRL Instance Document					(1)
101.SCH	XBRL Taxonomy Extension Schema Document					(1)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					(1)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					(1)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					(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

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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: November 14, 2013 /s/ Thomas H. McLain
Thomas H. McLain

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 14, 2013 /s/ Eric J. Schoen
Eric J. Schoen

Vice President, Finance and Chief Accounting Officer

(Principal Financial Officer)

INDEX OF EXHIBITS

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