VERMILLION, INC.
Form 10-Q
May 15, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
For the quarterly period ended March 31, 2013.

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)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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 x 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 x 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 x

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

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 x No ¨

As of April 30, 2013, the Registrant had 15,213,246 shares of common stock, par value $0.001 per share, outstanding.

Table of Contents

VERMILLION, INC.

FORM 10-Q

Table of Contents

Table of Contents

PART I - FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

Vermillion, Inc.

Consolidated Balance Sheets

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

(Unaudited)

	March 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 5,834	$ 8,007
Accounts receivable	184	137
Prepaid expenses and other current assets	359	348
Total current assets	6,377	8,492
Property and equipment, net	121	142
Other assets	8	
Total assets	$ 6,506	$ 8,634
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 794	$ 525
Accrued liabilities	964	1,074
Short-term debt	1,106	1,106
Deferred revenue	709	492
Total current liabilities	3,573	3,197
Deferred revenue	656	770
Total liabilities	4,229	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 March 31, 2013 and December 31, 2012, respectively		
Common stock, $0.001 par value, 150,000,000 shares authorized; 15,213,246 and 15,200,079 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	15	15
Additional paid-in capital	328,278	328,097
Accumulated deficit	(326,016)	(323,445)
Total stockholders equity	2,277	4,667
Total liabilities and stockholders equity	$ 6,506	$ 8,634

See accompanying notes to the consolidated financial statements.

Table of Contents

Vermillion, Inc.

Consolidated Statements of Operations and Comprehensive Loss

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

(Unaudited)

	Three Months Ended March 31, 2013	2012
Revenue:		
Product	$ 214	$ 198
License	114	114
Total revenue	328	312
Cost of revenue:		
Product	37	38
Total cost of revenue	37	38
Gross profit	291	274
Operating expenses:		
Research and development[(1)]	484	452
Sales and marketing[(2)]	1,072	1,518
General and administrative[(3)]	1,337	468
Total operating expenses	2,893	2,438
Loss from operations	(2,602)	(2,164)
Interest income	2	8
Interest expense		(65)
Gain on litigation settlement, net		379
Reorganization items		88
Other income (expense), net	29	(22)
Loss before income taxes	(2,571)	(1,776)
Income tax benefit (expense)		
Net loss	$ (2,571)	$ (1,776)
Net loss per share-basic and diluted	$ (0.17)	$ (0.12)
Weighted average common shares used to compute basic and diluted net loss per common share	15,201,616	14,903,455
Net loss	(2,571)	(1,776)
Foreign currency translation adjustment		(3)
Comprehensive loss	$ (2,571)	$ (1,779)
Non-cash stock-based compensation expense included in operating expenses:		
(1) Research and development	$ 20	$ 34
(2) Sales and marketing	54	36
(3) General and administrative	107	70

See accompanying notes to the consolidated financial statements.

Table of Contents

Vermillion, Inc.

Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Three Months Ended March 31, 2013	2012
Cash flows from operating activities:		
Net loss	$ (2,571)	$ (1,776)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash license revenue	(114)	(114)
Loss on sale and disposal of property and equipment		2
Depreciation and amortization	21	21
Stock-based compensation expense	176	138
Warrants issued for services	5	2
Changes in operating assets and liabilities:		
Accounts receivable	(47)	(15)
Prepaid expenses and other assets	(19)	(56)
Accounts payable, accrued liabilities and other liabilities	159	(976)
Deferred revenue	217	183
Reorganization Items		(30)
Net cash used in operating activities	(2,173)	(2,621)
Cash flows from investing activities:		
Purchase of property and equipment		(9)
Net cash flows used in investing activities:		(9)
Cash flows from financing activities:		
Proceeds from issuance of common stock from exercise of stock options		6
Net cash provided by financing activities		6
Effect of exchange rate changes on cash and cash equivalents		(3)
Net decrease in cash and cash equivalents	(2,173)	(2,627)
Cash and cash equivalents, beginning of period	8,007	22,477
Cash and cash equivalents, end of period	$ 5,834	$ 19,850
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest:	$	$ 65

See accompanying notes to the consolidated financial statements.

Table of Contents

Vermillion, Inc.

Notes to Consolidated Financial Statements

(Unaudited)

1. Organization, Basis of Presentation and Significant Accounting and Reporting Policies

Organization

Vermillion, Inc. (Vermillion) and its wholly-owned subsidiaries, collectively referred to as we or the Company , is incorporated in the state of Delaware, and is engaged in the business of developing and commercializing diagnostic tests in the fields of oncology, vascular medicine and women s health. In March 2010, we commercially launched OVA1 ovarian tumor triage test (OVA1). We distribute OVA1 through Quest Diagnostics Incorporated (Quest Diagnostics), a related party, which has 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.

Liquidity

We expect revenue relating to OVA1 to be our only material, recurring source of cash in 2013. 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.

On May 13, 2013, we completed a private placement of 8,000,000 shares of our common stock for estimated net proceeds of approximately $11,800,000. We issued 12,500,000 warrants in connection with this private placement. If these warrants are exercised, we would realize an additional $18,250,000 of net proceeds.

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, 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 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 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, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimated results.

Table of Contents

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, filed with the SEC on March 1, 2013.

2. Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board 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 our interim consolidated financial statements, but could require additional disclosure, if applicable, in future periods.

3. Secured Line of Credit with Quest Diagnostics Incorporated

On July 22, 2005, in connection with our Strategic Alliance Agreement with Quest Diagnostics (as amended, the Strategic Alliance Agreement), Quest Diagnostics provided us with a $10,000,000 secured line of credit, which was collateralized by certain of our intellectual property, to develop and commercialize up to three diagnostic tests from our product pipeline (the Strategic Alliance). Quest Diagnostics has selected two diagnostic tests to commercialize, a peripheral arterial disease blood test and OVA1. This secured line of credit also contains provisions for Quest Diagnostics to forgive portions of the amounts borrowed that correspond to our achievement of certain milestones related to development, regulatory approval and commercialization of certain diagnostic tests. The amounts to be forgiven and the corresponding milestones we must achieve are:

(i) $1,000,000 for each application that allows a licensed laboratory test to be commercialized, with a maximum of three applications for $3,000,000;

(ii) $3,000,000 for the earlier of the United States Food and Drug Administration (FDA) clearance of the first diagnostic test kit or commercialization of the first diagnostic test kit; and

(iii) $2,000,000 upon each FDA clearance of up to two subsequent diagnostic test kits but no later than the first commercialization of each such diagnostic test kit, with a maximum forgiveness of $4,000,000 for two diagnostic test kits.

If not otherwise forgiven, the principal amount outstanding of this secured line of credit became due and payable on October 7, 2012.

We achieved the milestone provision for an application that allows a licensed laboratory test to be commercialized when OVA1 was cleared by the FDA in September 2009. The agreement specifies that milestone reduces the secured line of credit by $1,000,000. On September 11, 2009, we achieved the FDA clearance of OVA1 milestone provision in the secured line of credit agreement providing for a reduction in the principal amount of the loan of $3,000,000. Recognition of both milestones reduced the outstanding principal amount to $6,000,000. However, Quest Diagnostics has disputed that the $1,000,000 milestone was met.

We have made monthly payments to Quest Diagnostics on the secured line of credit based on a principal balance of $7,000,000, which is in excess of the interest due on the expected $6,000,000 principal balance. We believe this resulted in a curtailment of the principal balance of $106,000. However, Quest Diagnostics has disputed that such additional principal curtailment has been made.

On October 12, 2012, we paid Quest Diagnostics approximately $5,894,000 of principal which we believe represents payment in full of all outstanding principal under the secured line of credit. We continue to show the amount of the liability as $1,106,000 as of March 31, 2013 given that Quest Diagnostics has disputed that the $1,000,000 milestone was met and the $106,000 principal curtailment has been made.

Table of Contents

4. Commitments 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 as of March 21, 2013, filed a verified complaint in the Delaware Court of Chancery (the Court) against Vermillion, each current member of our Board of Directors, and Gail S. Page. On June 1, 2012, Mr. Bessenyei and Mr. Goggin filed an amended verified complaint that was substantially similar to the verified complaint. The amended verified complaint contains the following causes of action: breach of fiduciary duty under two standards, declaratory relief, preliminary injunctive relief, and permanent injunctive relief. The allegations in the amended verified complaint challenge the adoption by the Board of Directors of an amendment to our bylaws eliminating the board seat formerly held by Ms. Page. As previously disclosed by Vermillion, on May 15, 2012, Ms. Page was terminated without cause as Vermillion s President and Chief Executive Officer, and, upon her termination, Ms. Page resigned her seat on the Board of Directors. For a variety of reasons, including an effort to streamline Vermillion s organization and extend its cash runway, the Board of Directors amended our bylaws to eliminate the vacant board seat, thereby reducing the size of the Board of Directors from seven to six members. This effort to streamline Vermillion s organization had begun in January 2012, when the Board of Directors amended the bylaws to eliminate an additional (eighth) seat on the Board of Directors. Mr. Bessenyei and Mr. Goggin claim that the Board of Directors decision to eliminate the seat on May 15, 2012 was a breach of its fiduciary duties, alleging that the Board of Directors actions were intended to prevent Mr. Bessenyei s and Mr. Goggin s nominees from both being able to be elected to the Board of Directors, and to entrench the Board of Directors current members. Among other things, Mr. Bessenyei and Mr. Goggin sought to have the Court declare null and void the May 15, 2012 amendment to the bylaws, and award to Mr. Bessenyei and Mr. Goggin the costs and fees incurred by them in the action.

The parties negotiated a scheduling order, which was approved on June 6, 2012, setting trial in this expedited action to start on July 31, 2012. On June 13, 2012, Vermillion and the other defendants filed an answer. The parties then engaged in extensive discovery, including document production, service of interrogatory responses, and the taking of depositions. On July 26, 2012, Vermillion and the other defendants filed a motion to dismiss the case arguing that plaintiffs and their counsel provided improperly notarized documents verifying the complaint, amended complaint and discovery responses. 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 filed their opening appellate brief on February 1, 2013. On February 12, 2013, the Delaware Supreme Court denied Vermillion and the other defendants motion to summarily affirm. The parties have filed their respective answering and reply appellate briefs and a hearing has been set for May 22, 2013.

György Bessenyei Annual Shareholder Meeting Litigation

On January 9, 2013, György B. Bessenyei, a stockholder of Vermillion, filed a verified complaint in the Court against Vermillion, and each current member of our Board of Directors. The complaint contains a cause of action for violation of Section 211 of the General Corporation Law of Delaware. The allegations in the complaint relate to the 2012 annual shareholder meeting which had not yet been held due to a scheduling order entered in the Goggin and Bessenyei litigation discussed above. The complaint seeks to have the Court compel Vermillion to hold its annual shareholder meeting and to award to Mr. Bessenyei the costs and fees incurred by him in the action. On January 16, 2013, the parties held a scheduling conference with the Court. On January 18, 2013, Vermillion filed its preliminary proxy setting the annual meeting date for March 21, 2013. Vermillion held its annual shareholder meeting as scheduled on March 21, 2013, Mr. Goggin was elected to the open seat on our Board of Directors, and the parties subsequently filed a stipulation of dismissal of the action on April 1, 2013.

In addition, from time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We establish reserves for specific liabilities in connection with legal actions that we deem to be probable and estimable. Other than as disclosed above, we are not currently a party to any proceeding, the adverse outcome of which would have a material adverse effect on our financial position or results of operations.

Table of Contents

5. Employee Benefits Plans

2010 Stock Option Plan

In February 2010, our Board of Directors approved the Vermillion, Inc. 2010 Stock Incentive Plan (the 2010 Plan), which was approved by our stockholders in December 2010. The 2010 Plan is administered by the Compensation Committee of the Board. The Company s employees, directors, and consultants are eligible to receive awards under 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 1,322,983 shares of common stock, par value $0.001 per share under the 2010 Plan, subject to adjustment as provided in the 2010 Plan. There were approximately 48,000 shares available for grant in the 2010 Plan at March 31, 2013.

Employee Stock-Based Compensation

We granted stock options to purchase 2,500 and 455,300 shares of common stock with an average exercise price of $1.22 and $1.62 during the three months ended March 31, 2013 and 2012, respectively.

In addition, 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, subject to approval by our stockholders of an increase in the number of shares authorized under our 2010 Stock Incentive Plan. The stock options vest in 48 equal monthly installments unless accelerated in accordance with the President and Chief Executive Officer s employment agreement. Pursuant to Accounting Standards Codification 718, Compensation Stock Compensation, there is no stock-based compensation expense recognized for President and Chief Executive Officer s grant until approval by our stockholders of an increase in the number of shares authorized under our 2010 Stock Incentive Plan.

During the three months ended March 31, 2013, we granted 11,500 restricted stock units with a fair value of $14,000 to a member of our Board of Director s as compensation for services rendered in the three months ended March 31, 2013. There were no restricted stock unit grants during the three months ended March 31, 2012.

The allocation of employee stock-based compensation expense by functional area for the three months ended March 31, 2013 and 2012 was as follows:

(in thousands)	Three Months Ended March 31, 2013	2012
Research and development	$ 18	$ 27
Sales and marketing	54	36
General and administrative	101	68
	$ 173	$ 131

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 1,124,583 and 1,544,945 potential common shares as of March 31, 2013 and 2012, respectively, that are antidilutive. Potential common shares include incremental shares of common stock issuable upon the exercise of outstanding stock options, common stock warrants and restricted stock awards.

7. Related Party Transactions

Quest Diagnostics

Quest Diagnostics is a stockholder and the holder of our secured line of credit (see Note 3). Accounts receivable from Quest Diagnostics under the Strategic Alliance Agreement totaled $184,000 and $137,000 at March 31, 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 and was paid $200 per hour. For the years ended

Table of Contents

December 31, 2012 and 2011, the total amount of consulting fee expense for Mr. Huebner was $5,000 and $9,000, respectively. 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 will assist as needed to aid in the integration and transition of our new President and Chief Executive Officer. Mr. Huebner will be paid $15,000 per month until the Consulting Agreement expires or is terminated, prorated for partial months. For any services in excess of forty hours per week (on average) provided during a month, the Company will pay Mr. Huebner at the rate of $250 per hour. The 2013 Consulting Agreement, which is cancelable upon notice by either party, has an initial term of three (3) months, after which it may be extended by mutual agreement. For the three months ended March 31, 2013, the total amount of consulting fee expense for Mr. Huebner was $7,500. Mr. Huebner was elected as Chairman of the Board of Directors, also on March 18, 2013.

We currently have no other consulting agreements with directors, officers or former directors and officers of the Company.

8. Subsequent Events

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 12,500,000 warrants at a price per warrant of $0.125 in the private placement. The net proceeds of the private placement were approximately $11,800,000 after deducting expected offering expenses. The Warrants are exercisable for 12,500,000 shares of common stock at $1.46 per share.

Table of Contents

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward Looking Statements

The Company has made statements in this Quarterly Report on Form 10-Q that are deemed forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. We claim the protection of such safe harbor, and disclaim any intent or obligation to update any forward-looking statement. You can identify these statements by forward-looking words such as may, expect, intend, anticipate, believe, estimate, plan, could, should and continue or the negative of these or similar words. These forward-looki statements may also use different phrases. We have based these forward-looking statements on management s (for purposes of this Item 2, we , us or our) current expectations and projections about future events. 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 automated 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;

forgiveness of the outstanding principal amounts of the secured line of credit by Quest Diagnostics;

commercialization of tests through and recognition of revenue under our agreement with Quest Diagnostics;

the amount of funding 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;

the consolidation of holdings of our common stock in the hands of fewer investors; and

our ability to obtain and expected reimbursement for our products 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 in Part II Item 1A, Risk Factors , 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 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

Table of Contents

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. 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. The results of the clinical trial demonstrated that in a clinical 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.

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 OVA 500 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%

Table of Contents

(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 OVA500 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 in March 2013 which has been submitted to a medical journal (not yet published). 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 National Comprehensive Cancer Network, an alliance of 21 major cancer centers with expert panels that analyze, research and recommend 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 stick to the 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.

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)

In addition to OVA1, we have development programs in other clinical aspects of ovarian cancer as well as in peripheral arterial disease. In the field of peripheral arterial disease, we have identified candidate biomarkers that may help to identify individuals at high risk for a decreased ankle-brachial index score, which is indicative of the likely presence of peripheral arterial disease. We have completed an intended-use study, published in the December 2012 edition of *Vascular Medicine*, to develop and validate a multi-marker algorithm for the assessment of individuals at risk for peripheral arterial disease. This algorithm will be specifically directed at a primary care population in which the peripheral arterial disease blood test is expected to be used. With our recent decision to focus on gynecologic oncology and related diseases, we now plan to seek a Development/Commercial Partner for this program who will work with us to complete the product development, conduct the required clinical validation studies, and eventually commercialize this product on a global basis.

In another program, we have initiated pilot experiments intended to identify markers with high clinical specificity that may complement OVA1. These experiments are early stage and may take different directions depending on the results. We have yet to select one or more intended uses, and establish a regulatory pathway for this potential next generation OVA product.

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; and the University of Kentucky.

The Medicare contractor Highmark Medicare Services (now Novitas Solutions) has been covering OVA1 in its reimbursement program since March 2010. There are currently twenty-five independent BlueCross BlueShield plans, representing approximately 45.2 million lives, which provide coverage for OVA1. In total, including Medicare and other private payers, approximately 91.7 million patients have access and coverage for OVA1. The Company and Quest Diagnostics are pursuing coverage from additional payers.

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. Approximately 1.4 million uniformed service members now have access to OVA1 through the Quest Diagnostics lab services contract with the Department of Defense, bringing the covered lives total to over 93 million.

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 kicks off 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 cover OVA1 testing. 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.

Table of Contents

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. 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.

Under the terms of our Strategic Alliance Agreement with Quest Diagnostics, Quest Diagnostics is 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 as amended. Quest Diagnostics is 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. OVA1 was CE-marked in September 2010, a requirement for marketing the test in the European Union. OVA1 was launched in India in May 2011. Quest Diagnostics has the right to extend its exclusivity period for an additional year beyond September 11, 2014 on the same terms and conditions.

In March 2012, the American Medical Association (AMA) Current Procedural Terminology (CPT®) Panel voted to approve an application for a Category I CPT code for OVA1, which became effective January 1, 2013. The new CPT code is a positive step forward in advancing the commercialization of OVA1, as we believe it helps streamline claims processing and accelerate further coverage and adoption by private payers.

On January 3, 2013, we received a letter (the Delisting Notice) from the NASDAQ Stock Market LLC (NASDAQ) notifying us that we were not in compliance with NASDAQ s Listing Rule 5620(a), which requires the Company to hold an annual meeting of shareholders no later than one year after the end of the Company s fiscal year-end, and Listing Rule 5620(b), which requires the Company to solicit proxies and provide proxy statements for such meeting and to provide copies of such proxy solicitation to NASDAQ. The annual meeting was delayed due to a lawsuit brought against the Company and its board of directors by dissident stockholders, Gyorgy B. Bessenyei and Robert S. Goggin, III, which prohibited the Company from holding a meeting until the matter was resolved. We held our annual meeting of shareholders on March 21, 2013 and are back in compliance with the NASDAQ listing rules.

On March 18, 2013, we appointed Thomas H. McLain as President and Chief Executive Officer. Mr. McLain most recently served as Chief Executive Officer and Chief Financial Officer of Claro Scientific, LLC, an early-stage diagnostic company. Before Claro, from 1998 to 2007 he held various senior management positions at Nabi Biopharmaceuticals (now Biota Pharmaceuticals, Inc.), a biotechnology company addressing immune system conditions. Prior to Nabi, Mr. McLain held several senior management positions of increasing responsibility over 10 years at Bausch & Lomb Incorporated, a global eye care company. Mr. McLain also previously served Eastman Chemical Company as a member of its board of directors, the audit and finance committees, and as chairman of the health, safety, environment and security committee. Mr. McLain previously served as a member of the board of the biotechnology industry association (BIO), as well as several community and business development boards. Earlier in his career, Mr. McLain served as Audit Manager at Ernst & Young, LLP. He holds an MBA in Accounting and Information Systems from the University of Rochester, Simon Graduate School of Business and a BA in economics from the College of the Holy Cross.

Effective March 18, 2013, the Company and Thomas H. McLain entered into an employment agreement (the Employment Agreement). Pursuant to the terms of the Employment Agreement, the Company will pay Mr. McLain an annual base salary of at least $350,000. In addition, Mr. McLain will be eligible for a bonus of up to fifty percent (50%) of his base salary (prorated for partial years) for achievement of reasonable Company and individual performance-related goals to be defined by the Company s Board of Directors. In addition, Mr. McLain is eligible to receive a one-time milestone incentive bonus of $50,000 that will be paid within thirty (30) days after the successful completion of a fund raising event of a minimum net to Vermillion of $4 million. In the event Mr. McLain is terminated without cause or for good reason , as those terms are defined in the Employment Agreement, at any time following the date which is six (6) months following the Effective Date, he is entitled to receive continued payment of his base salary as then in effect, as well as continued health and dental benefits, for a period of twelve months following the date of termination. In addition, pursuant to the Employment Agreement, in the event Mr. McLain is terminated without cause or for good reason within twelve (12) months following a change of control , as those terms are defined in the Employment Agreement, one-hundred percent (100%) of any then-unvested shares under Company stock options then held by Mr. McLain will vest upon the date of such termination.

Table of Contents

On March 18, 2013, Mr. McLain was granted an option to purchase 400,000 shares of the Company s common stock, subject to approval by the Company s stockholders of an increase in the number of shares authorized under the Company s 2010 Stock Incentive Plan. The options will vest in forty-eight (48) equal monthly installments, with the first installment vesting on April 1, 2013, and subject to acceleration upon a change in control, as defined in his Employment Agreement.

Mr. McLain succeeded Bruce Huebner, the company s interim president and chief executive officer. Mr. Huebner was elected as Chairman of the Board of Directors, also on March 18, 2013.

On March 21, 2013, Robert S. Goggin, III, a partner with Keller and Goggin, PC, was elected to our Board of Directors at our Annual Stockholder Meeting.

On May 6, 2013, we received notification that 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 automated platform, and as part of the consolidation we expect to substitute a new immunoassay component kit for the discontinuing kit. 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. At present, we anticipate this project will be completed well before December 2014 and expect that no material business interruption will result. However, no assurances can be made that the FDA will clear our expected 510(k) submission.

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 12,500,000 warrants at a price per warrant of $0.125 in the private placement. The net proceeds of the private placement were approximately $11,800,000 after deducting expected offering expenses. The Warrants are exercisable for 12,500,000 shares of common stock at $1.46 per share.

On May 10, 2013, the Board of Directors amended the Company s bylaws, effective immediately, to increase the number of directors of the Company from six to eight persons, creating two new director positions. Both new director positions will be Class III directors. The increase was required under the Shareholders Agreement between the Company and the investors named therein dated May 13, 2013 in conjunction with the recently announced private placement of common stock and warrants.

Critical Accounting Policies and Significant Estimates

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, filed with the SEC on March 1, 2013.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board 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 our interim consolidated financial statements, but could require additional disclosure, if applicable, in future periods.

Table of Contents

Results of Operations - Three Months Ended March 31, 2013 Compared to Three Months Ended March 31, 2012

The selected summary financial and operating data of Vermillion for the three months ended March 31, 2013 and 2012 were as follows:

(dollars in thousands)	Three Months Ended March 31, 2013	2012	Increase (Decrease) Amount	%
Revenue:				
Product	$ 214	$ 198	$ 16	8
License	114	114		
Total revenue	328	312	16	5
Cost of revenue:				
Product	37	38	(1)	(3)
Total cost of revenue	37	38	(1)	(3)
Gross profit	291	274	17	6
Operating expenses:				
Research and development	484	452	32	7
Sales and marketing	1,072	1,518	(446)	(29)
General and administrative	1,337	468	869	186
Total operating expenses	2,893	2,438	455	19
Loss from operations	(2,602)	(2,164)	(438)	20
Interest income	2	8	(6)	(75)
Interest expense		(65)	65	100
Gain on litigation settlement, net		379	(379)	(100)
Reorganization items		88	(88)	(100)
Other income (expense), net	29	(22)	51	(232)
Loss before income taxes	(2,571)	(1,776)	(795)	45
Income tax benefit (expense)				
Net loss	$ (2,571)	$ (1,776)	$ (795)	45

Product Revenue. Product revenue was $214,000 for the three months ended March 31, 2013 compared to $198,000 for the same period in 2012. We recognized product revenue for the three months ended March 31, 2013 for the sale of OVA1 through Quest Diagnostics. Quest Diagnostics performed approximately 4,274 OVA1 tests during the three months ended March 31, 2013 compared to approximately 3,952 tests for the same period in 2012. Product revenue increased for the three months ended March 31, 2013 compared to the same period in 2012 due to the increased volume of tests. We commercially launched OVA1 in March 2010 and product revenue for the three months ended March 31, 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 March 31, 2013 were consistent with the same period in 2012. However, we expect research and development expense to increase in future periods as we continue to invest in our product pipeline and progress 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. Our personnel-related expenses include the cost of our

territory development managers, the subject matter experts responsible for market development and the coordination of interactions with the Quest Diagnostics sales team. Sales and marketing expenses decreased $446,000, or 29%,

Table of Contents

for the three months ended March 31, 2013 compared to the same period in 2012. The decrease was primarily due to marketing and creative services consulting expense totaling $255,000 in the prior year that was not repeated in 2013. In addition, personnel and personnel-related costs decreased $172,000 compared to the same period in the prior year due to lower average headcount during the period due to our sales force restructuring in early 2012 .

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 $869,000, or 186%, for the three months ended March 31, 2013 compared to the same period in 2012. The increase was due to $151,000 in Annual Shareholder Meeting and proxy solicitation costs (no similar costs in 2012) as well as an increase of $70,000 in legal fees, primarily related to our contested proxy. Personnel related costs increased $150,000 for the cost of our CEO transition compared to the same period in 2012. In addition, the prior year period included one-time reversals of $440,000 of amounts previously accrued for litigation which was settled in 2012. We expect our general and administrative expenses to decrease in future periods as the one-time costs of the Annual Shareholder Meeting and CEO transition during the three months ended March 31, 2013 are not expected to recur.

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

Gain on Litigation Settlement, Net. In February 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 was $1,000,000; $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 in September 2012. The gain on litigation settlement represents the net proceeds received from the March 2012 payment.

Reorganization Items. There were no reorganization items for the three months ended March 31, 2013 compared to income of $88,000 for the same period in 2012. The prior year amount was due primarily to the one-time recognition of $103,000 in claims adjustments upon the formal closure of our Bankruptcy Filing in January 2012.

Liquidity and Capital Resources

In March 2010, we launched OVA1 commercially. We will 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, 2013, we had an accumulated deficit of $326,016,000 and stockholders equity of $2,227,000. As of March 31, 2013, we had $5,834,000 of cash and cash equivalents and $3,573,000 of current liabilities.

We expect revenue relating to OVA1 to be our only material, recurring source of cash in 2013. 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.

On May 13, 2013, we completed a private placement of 8,000,000 shares of our common stock for estimated net proceeds of approximately $11,800,000. We issued 12,500,000 warrants in connection with this private placement. If these warrants are exercised, we would realize an additional $18,250,000 of net proceeds.

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.

Table of Contents

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.

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.

Cash and cash equivalents as of March 31, 2013 and December 31, 2012, were $5,834,000 and $8,007,000, respectively. Working capital was $2,804,000 and $5,295,000 at March 31, 2013 and December 31, 2012, respectively.

Net cash used in operating activities was $2,173,000 for the three months ended March 31, 2013, resulting primarily from $2,571,000 net loss incurred as adjusted for non-cash license revenues of $114,000, partially offset by $176,000 of stock-based compensation expense. Net cash used in operating activities also included $360,000 of cash provided by changes in operating assets and liabilities mainly driven by the $159,000 increase of accounts payable, accrued liabilities and other liabilities and the $217,000 increase in deferred revenue.

Net cash used in operating activities was $2,621,000 for the three months ended March 31, 2012, resulting primarily from $1,776,000 net loss incurred as adjusted for non-cash license revenues of $114,000, partially offset by $138,000 of stock-based compensation expense. Net cash used in operating activities also included $894,000 of cash used from changes in operating assets and liabilities mainly driven by the $976,000 decrease of accounts payable, accrued liabilities and other liabilities.

There was no net cash used in investing activities for the three months ended March 31, 2013. Net cash used in investing activities was $9,000 for the three months ended March 31, 2012 due to the purchase of property and equipment.

There was no net cash provided by financing activities for the three months ended March 31, 2013. Net cash provided by financing activities was $6,000 for the three months ended March 31, 2012, which resulted from net proceeds from issuance of common stock from exercise of stock options.

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

Table of Contents

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-15e and 15d-15e 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 or officers and principal financial officer or officers, 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 under the Exchange Act as of March 31, 2013. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of March 31, 2013, our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15(d)-15(e) under the Exchange Act, 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.

Table of Contents

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 as of March 21, 2013, filed a verified complaint in the Delaware Court of Chancery (the Court) against Vermillion, each current member of our Board of Directors, and Gail S. Page. On June 1, 2012, Mr. Bessenyei and Mr. Goggin filed an amended verified complaint that was substantially similar to the verified complaint. The amended verified complaint contains the following causes of action: breach of fiduciary duty under two standards, declaratory relief, preliminary injunctive relief, and permanent injunctive relief. The allegations in the amended verified complaint challenge the adoption by the Board of Directors of an amendment to our bylaws eliminating the board seat formerly held by Ms. Page. As previously disclosed by Vermillion, on May 15, 2012, Ms. Page was terminated without cause as Vermillion s President and Chief Executive Officer, and, upon her termination, Ms. Page resigned her seat on the Board of Directors. For a variety of reasons, including an effort to streamline Vermillion s organization and extend its cash runway, the Board of Directors amended our bylaws to eliminate the vacant board seat, thereby reducing the size of the Board of Directors from seven to six members. This effort to streamline Vermillion s organization had begun in January 2012, when the Board of Directors amended the bylaws to eliminate an additional (eighth) seat on the Board of Directors. Mr. Bessenyei and Mr. Goggin claim that the Board of Directors decision to eliminate the seat on May 15, 2012 was a breach of its fiduciary duties, alleging that the Board of Directors actions were intended to prevent Mr. Bessenyei s and Mr. Goggin s nominees from both being able to be elected to the Board of Directors, and to entrench the Board of Directors current members. Among other things, Mr. Bessenyei and Mr. Goggin sought to have the Court declare null and void the May 15, 2012 amendment to the bylaws, and award to Mr. Bessenyei and Mr. Goggin the costs and fees incurred by them in the action.

The parties negotiated a scheduling order, which was approved on June 6, 2012, setting trial in this expedited action to start on July 31, 2012. On June 13, 2012, Vermillion and the other defendants filed an answer. The parties then engaged in extensive discovery, including document production, service of interrogatory responses, and the taking of depositions. On July 26, 2012, Vermillion and the other defendants filed a motion to dismiss the case arguing that plaintiffs and their counsel provided improperly notarized documents verifying the complaint, amended complaint and discovery responses. 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 filed their opening appellate brief on February 1, 2013. On February 12, 2013, the Delaware Supreme Court denied Vermillion and the other defendants motion to summarily affirm. The parties have filed their respective answering and reply appellate briefs and a hearing has been set for May 22, 2013.

György Bessenyei Annual Shareholder Meeting Litigation

On January 9, 2013, György B. Bessenyei, a stockholder of Vermillion, filed a verified complaint in the Delaware Court of Chancery (the Court) against Vermillion, and each current member of our Board of Directors. The complaint contains a cause of action for violation of Section 211 of the General Corporation Law of Delaware. The allegations in the complaint relate to the 2012 annual shareholder meeting which had not yet been held due to a scheduling order entered in the Goggin and Bessenyei litigation discussed above. The complaint seeks to have the Court compel Vermillion to hold its annual shareholder meeting and to award to Mr. Bessenyei the costs and fees incurred by him in the action. On January 16, 2013, the parties held a scheduling conference with the Court. On January 18, 2013, Vermillion filed its preliminary proxy setting the annual meeting date for March 21, 2013. Vermillion held its annual shareholder meeting as scheduled on March 21, 2013, Mr. Goggin was elected to the open seat on our Board of Directors, and the parties subsequently filed a stipulation of dismissal of the action on April 1, 2013.

Table of Contents

Item 1A. Risk Factors

You should carefully consider the following risk factors and uncertainties together with all of the other information contained in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2012, including the audited consolidated financial statements and accompanying notes, and our other filings from time to time with the SEC. The risks and uncertainties management describes below are the only material ones we face as of the date this Quarterly Report on Form 10-Q is initially filed with the SEC. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also adversely affect our business.

Risks Related to Our Business

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

We have experienced significant operating losses each year since our inception and we expect to incur a net loss for fiscal year 2013 and the foreseeable future. Our losses have resulted principally from costs incurred in research and development, sales and marketing, litigation, and general and administrative costs.

All of our revenues are currently generated from sales of OVA1 tests performed by Quest Diagnostics. If we are unable to increase the volume of OVA1 sales, our consolidated results of operations and financial condition would be adversely affected.

We expect that for the foreseeable future nearly all of our revenue will be derived from Quest Diagnostics and will depend on the number of OVA1 tests performed by Quest Diagnostics and the reimbursement rate for performing those tests, which are outside of our control.

We expect that nearly all of our revenues for the foreseeable future will be derived through our strategic partnership with Quest Diagnostics and will be based on the number of OVA1 tests performed by Quest Diagnostics and the reimbursement rate received by Quest Diagnostics for those tests. Under the terms of our Strategic Alliance Agreement with Quest Diagnostics, we are to be paid $50 for each domestic OVA1 performed by Quest Diagnostics, as well as a 33% royalty of Quest Diagnostics gross margin from performing OVA1. The Agreement provides for a monthly payment by Quest Diagnostics to us based on Quest Diagnostics average reimbursement per OVA1 in the previous month, and the royalty portion of our revenue is subject to adjustment, either up or down, on an annual basis within 60 days of end of each calendar year based on Quest Diagnostics actual reimbursement history for that calendar year. To the extent Quest Diagnostics is not reimbursed, is reimbursed at a lower than expected rate, or has reimbursement claims rejected, the royalty amounts owed to us would be reduced. Any amounts owed by us to Quest Diagnostics will be deducted against payments owed to us in future periods. The number of tests performed by Quest Diagnostics and the amount of reimbursements received by Quest Diagnostics in any given period is largely outside of our control, and Quest Diagnostics has many other test products that it promotes in addition to OVA1, which could result in a reduced focus by Quest Diagnostics on promoting OVA1. If Quest Diagnostics does not experience growing OVA1 test volumes or receives less reimbursement per test than expected, it could have a material adverse effect on our revenue, results of operations and cash flows.

How we will recognize future revenue under the Quest Diagnostics Strategic Alliance Agreement remains uncertain and is likely to change, which could affect our revenue in future periods.

Given our limited commercialization history with OVA1 and our inability to know or control Quest Diagnostics reimbursement rates for OVA1, it is difficult for us to estimate future royalties and the size of any year-end adjustment calculated by Quest Diagnostics within 60 days of every calendar year end as required by the Strategic Alliance Agreement with Quest Diagnostics. Therefore, it is difficult for us to recognize some or all of the revenue related to the royalty payments to be received from Quest Diagnostics during the calendar year until we are better able to estimate the final royalty payment amounts and the magnitude and effect of the annual recalculation and adjustment mechanism. Accordingly, the amount of revenue we will be able to recognize in any quarter could vary significantly, and the method used to calculate that revenue could be subject to change.

Failures by third party payers to reimburse OVA1 or changes or variances in reimbursement rates could materially and adversely affect our revenues and could result in significant fluctuations in our revenues.

Most of our revenue is dependent on the amount Quest Diagnostics receives from third party payers for performing OVA1 tests. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to

Table of Contents

change and particularly volatile during the early stages of commercialization. There remain questions as to what extent third party payers, like Medicare, Medicaid and private insurance companies will provide coverage for OVA1 and for which indications. The reimbursement rates for OVA1 are largely out of our control, as Quest Diagnostics handles all reimbursements of OVA1 performed. We have limited visibility into any specific payer-level reimbursement data for OVA1 as such data is provided to us by Quest once a year as part of the annual revenue true-up process. We endeavor to maintain a dialogue with Quest Diagnostics regarding reimbursement issues as they arise. Quest Diagnostics has advised us that it has experienced volatility in the coverage and reimbursement of OVA1 due to contract negotiation with third party payers and implementation requirements and that the reimbursement amounts it has received from third party payers varies from payer to payer, and, in some cases, the variation is material. Third party payers, including private insurance companies as well as government payers such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostic test industry. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in the reimbursement rate of payers may occur in the future. Reductions in the price at which OVA1 is reimbursed could have a material adverse effect on our revenues. If we and Quest Diagnostics are unable to establish and maintain broad coverage and reimbursement for OVA1 or if third party payers change their coverage or reimbursement policies with respect to OVA1, our revenues could be materially and adversely affected.

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

In order to continue our operations through 2013 and beyond, we may need to raise additional capital. Our independent registered public accounting firm s report on our financial statements for the year ended December 31, 2012 includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern, given our recurring net losses and negative cash flows from operations. In the event that the warrants issued by us on May 13, 2013 are exercised by the holders in full, we would have an additional net proceeds of $18.25 million however there is no guarantee that such warrants will be exercised prior to their maturity, and in any event, the holders are not permitted to exercise the warrants prior to the 90th day following the issuance date. In the event that the warrants are not exercised, we may need to raise capital. We may seek to raise additional capital through the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. The availability of financing opportunities will depend, in part, on market conditions, and the outlook for our business. Any future issuance of equity securities or securities convertible into equity could result in substantial dilution to our stockholders, and the securities issued in such a financing may have rights, preferences or privileges senior to those of our common stock. In addition, in the event that the warrants are exercised in full, we will be required to issue an additional 12.5 million shares of common stock, which will involve substantial dilution to shareholders. If we raise additional funds by issuing debt, we may be subject to limitations on our operations, through debt covenants or other restrictions. If we obtain additional funds through arrangements with collaborators or strategic partners, we may be required to relinquish rights to certain technologies or products that we might otherwise seek to retain. If adequate and acceptable financing is not available to us at the time that we seek to raise additional capital, our ability to execute our business plan successfully may be negatively impacted.

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

Our success depends on our ability to continue to develop and commercialize diagnostic products. There is considerable risk in developing diagnostic products based on our biomarker discovery efforts, as candidate biomarkers may fail to validate results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. For example, markers being evaluated for one or more next-generation ovarian cancer diagnostic tests may not be validated in downstream pre-clinical or clinical studies, once we undertake and perform such studies. It is also possible that the biomarkers in our Peripheral artery disease (PAD) blood test in development, upon further analysis and clinical study, may not meet acceptance criteria for validation or regulatory clearance.

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

Table of Contents

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

- our ability to convince the medical community of the safety and clinical efficacy of our products and their advantages over existing diagnostic products;
- our success in establishing new clinical practices or changing previous ones, such that utilization of the tests fail to meet established standards of care, medical guidelines and the like;
- our ability to further establish business relationships with other diagnostic or laboratory companies that can assist in the commercialization of these products in the US and globally; and
- the scope and extent of the agreement by Medicare and third-party payers to provide full or partial reimbursement coverage for our products, which will affect patients willingness to pay for our products and will likely heavily influence physicians decisions to recommend or use our products.

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

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

Our principal competition currently comes from the many clinical options available to medical personnel involved in clinical decision making. For example, rather than ordering an OVA1 for a woman with an adnexal mass, obstetricians, gynecologists, and gynecologic oncologists may choose a different clinical option or none at all. If we are not able to convince clinicians that OVA1 provides significant improvement over current clinical practices, our ability to commercialize OVA1 would be adversely affected. Additionally, Fujirebio Diagnostics, Inc. announced in September 2011 that they received clearance from the FDA to commercialize its Risk of Malignancy Algorithm (ROMA) test. The ROMA test is in direct competition with OVA1 and our revenues could be materially and adversely affected if and when the ROMA test is successfully commercialized. In addition, competitors, such as Becton Dickinson, ArrayIt Corporation, and Abbott Labs have publicly disclosed that they have been or are currently working on ovarian cancer diagnostic assays. Academic institutions periodically report new findings in ovarian cancer diagnostics that may have commercial value. Our failure to compete with any competitive diagnostic assay if and when commercialized could adversely affect our business.

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

The commercialization of our diagnostic tests may be affected adversely by changing FDA regulations, and any delay by or failure of the FDA to approve our diagnostic tests submitted to the FDA may adversely affect our consolidated revenues, results of operations and financial condition.

The FDA cleared OVA1 in September 2009. Our activities related to diagnostic products are, or have the potential to be, subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of our products. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

The Food, Drug and Cosmetic Act requires that medical devices introduced to the United States market, unless exempted by regulation, be the subject of either a pre-market notification clearance, known as a 510(k) clearance or 510(k) de novo clearance, or a PMA. Some of our potential

future clinical products may require a 510(k) or 510(k) de novo clearance, while others may require a PMA. With respect to devices reviewed through the 510(k) process, we may not market a device until an order is issued by the FDA finding our product to be substantially equivalent to a legally marketed device known as a predicate device. A 510(k) submission may involve the presentation of a substantial volume of data, including clinical data. The FDA may agree that the product is substantially equivalent to a predicate device and allow the product to be marketed in the United States. On the other

Table of Contents

hand, the FDA may determine that the device is not substantially equivalent and require a PMA, or require further information, such as additional test data, including data from clinical studies, before it is able to make a determination regarding substantial equivalence. By requesting additional information, the FDA can delay market introduction of our products. Delays in receipt of or failure to receive any necessary 510(k) clearance or PMA approval, or the imposition of stringent restrictions on the labeling and sales of our products, could have a material adverse effect on us. If the FDA indicates that a PMA is required for any of our potential future clinical products, the application will require extensive clinical studies, manufacturing information and likely review by a panel of experts outside the FDA. Clinical studies to support either a 510(k) submission or a PMA application would need to be conducted in accordance with FDA requirements. Failure to comply with FDA requirements could result in the FDA s refusal to accept the data or the imposition of regulatory sanctions. We cannot assure that any necessary 510(k) clearance or PMA approval will be granted on a timely basis, or at all. To the extent we seek FDA 510(k) clearance or FDA pre-market approval for other diagnostic tests, any delay by or failure of the FDA to clear or approve those diagnostic tests may adversely affect our consolidated revenues, results of operations and financial condition.

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

The commercialization of our products could be delayed, halted or prevented by applicable FDA regulations. If the FDA were to view any of our actions as non-compliant, it could initiate enforcement actions, such as a warning letter and possible imposition of penalties. In addition, analyte specific reagents that we may provide would be subject to a number of FDA requirements, including compliance with the FDA s Quality System Regulations (QSR), which establish extensive requirements for quality assurance and control as well as manufacturing procedures. Failure to comply with these regulations could result in enforcement actions for us or our potential suppliers. Adverse FDA actions in any of these areas could significantly increase our expenses and limit our revenue and profitability. We will need to undertake steps to maintain our operations in line with the FDA s QSR requirements. Some components of OVA1 are manufactured by other companies and we are required to maintain supply agreements with these companies. If these agreements are not satisfactory to the FDA, we will have to renegotiate these agreements. Any failure to do so would have an adverse effect on our ability to commercialize OVA1. Our suppliers manufacturing facilities will be subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. If and when we begin commercializing and assembling our products by ourselves, our facilities will be subject to the same inspections. We or our suppliers may not satisfy such regulatory requirements, and any such failure to do so would have an adverse effect on our commercialization efforts.

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

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

On May 6, 2013, we received notification that one of the five immunoassay component kits that are used in OVA1 is to be discontinued effective December 2014. To address this issue, we are planning on consolidating the five OVA1 immunoassays onto a single mainstream automated platform, and as part of the consolidation substituting a new immunoassay component kit for the discontinuing kit. These changes will require a 510(k) submission with the FDA. No assurances can be made that the FDA will clear our expected 510(k) submission approving these changes to OVA1 prior to December 2014, or at all.

Table of Contents

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

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

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

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

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

Our success depends in part on our ability to maintain and enforce our proprietary rights. We rely on a combination of patents, trademarks, copyrights and trade secrets to protect our technology and brand. We have submitted a number of patent applications covering biomarkers that may have diagnostic or therapeutic utility. Our patent applications may or may not result in additional patents being issued.

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

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

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

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

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

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

An unfavorable judgment against us in any legal proceeding or claim could require us to pay monetary damages. In addition, an unfavorable judgment in which the counterparty is awarded equitable relief, such as an injunction, could have an adverse impact on our licensing and

sublicensing activities, which could harm our business, consolidated results of operations and consolidated financial condition.

Table of Contents

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

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

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

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

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

Business interruptions could limit our ability to operate our business.

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

If we fail to maintain proper and effective internal controls because of changes in our operations from developing and commercializing our present and future products, our ability to produce accurate and timely financial statements could be impaired, which could adversely affect our business, operating results, and financial condition.

We are required to comply with the management certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We are required to report, among other things, control deficiencies that constitute a material weakness or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A material weakness is a deficiency or combination of deficiencies that results in a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected. If we fail to continue to comply with the requirements of Section 404, we might be subject to sanctions or investigation by regulatory authorities such as the SEC. If we fail to remedy any material weakness, our consolidated financial statements may be inaccurate, which could adversely affect our business, operating results, and financial condition.

Legislative actions resulting in higher compliance costs are likely to adversely affect our future consolidated results of operations, financial position and cash flows.

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

Table of Contents

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

In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), which makes changes that are expected to significantly impact the pharmaceutical and medical device industries. Beginning in 2013, each medical device manufacturer will have to pay a sales tax in an amount equal to 2.3 percent of the price for which such manufacturer sells its medical devices. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. This adjustment is in addition to a productivity adjustment to the Clinical Laboratory Fee Schedule. In addition to the PPACA, the impact of which cannot be predicted given its recent enactment and current lack of implementing regulations or interpretive guidance, a number of states are also contemplating significant reform of their healthcare policies. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation may result in decreased profits to us, and lower reimbursements by payers for our tests, all of which may adversely affect our business.

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

We are subject to various international, federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, the recycling and treatment of electrical and electronic equipment, and emissions and discharges into the environment. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We are also subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs to remediate hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, as well as incur liability to third parties affected by such contamination. The presence of, or failure to remediate properly, such substances could adversely affect the value and the ability to transfer or encumber such property. Based on currently available information, although there can be no assurance, we believe that such costs and liabilities have not had and will not have a material adverse impact on our consolidated results of operations.

Risks Related to Owning our Stock

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

The liquidity and trading volume of our common stock has at times been low in the past and may again be low in the future. If the liquidity and trading volume were to fall, this could impact the trading price of our shares and adversely affect our ability to issue stock and for holders to obtain liquidity in their shares should they desire to sell. The issuance of common stock by us on May 13, 2013, involved a significant issuance of stock to a limited number of investors, significantly increasing the concentration of our share ownership in a few holders. In addition, the issuance of common stock was done on a private basis and is not expected to increase the trading volume in our common stock for some period of time.

Our stock price has been, and may continue to be, highly volatile, and an investment in our stock could suffer a decline in value.

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

- failure to significantly increase revenue and volumes of OVA1;
- actual or anticipated period-to-period fluctuations in financial results;
- failure to achieve, or changes in, financial estimates by securities analysts;
- announcements or introductions of new products or services or technological innovations by us or our competitors;

publicity regarding actual or potential discoveries of biomarkers by others;

comments or opinions by securities analysts or stockholders;

conditions or trends in the pharmaceutical, biotechnology and life science industries;

Table of Contents

announcements by us of significant acquisitions and divestitures, strategic partnerships, joint ventures or capital commitments;

developments regarding our patents or other intellectual property or that of our competitors;

litigation or threat of litigation;

additions or departures of key personnel;

limited daily trading volume;

announcements of financing transactions;

economic and other external factors, disasters or crises; and

our announcement of additional fund raisings.

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

If we fail to meet all applicable NASDAQ Capital Market requirements and NASDAQ determines to delist our common stock, the market liquidity and market price of our common stock could decline, and our ability to access the capital markets could be negatively affected.

In order to maintain the listing on the *NASDAQ* Capital Market, we must satisfy minimum financial and other requirements, including requirements that we maintain a minimum stockholders equity of $2.5 million and a minimum bid price of $1 per share. If we fail to meet all applicable *NASDAQ* Capital Market requirements and *NASDAQ* determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and adversely affect our ability to obtain financing for the continuation of our operations. This delisting could also impair the value of our investors investment. While our equity financing transaction consummated on May 13, 2013, is expected to increase our minimum stockholders equity above the minimum threshold, there is no guarantee that the NASDAQ will approve our listing application for the additional shares of common stock issued in the transaction and the shares issuable upon exercise of the warrants. If the NASDAQ were to not approve our listing application, we may be required to delist our stock from the NASDAQ Capital Market.

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

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us, even if doing so might be deemed beneficial by our stockholders. In connection with our offering of common stock and warrants on May 13, 2013, we entered into a shareholders agreement which includes agreements limiting our ability to enter into acquisition and other transactions. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company.

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

Certain of our stockholders may, from time to time, attempt to aggressively involve themselves in the governance and strategic direction of our Company above and apart from normal interactions between stockholders and management. Such activism, and any related negative publicity, could result in substantial costs that negatively impact our stock price and increase its volatility. In addition, such activism could cause a

diversion of the attention of our management and Board of Directors and create perceived uncertainties with existing and potential strategic partners impacting our ability to consummate potential transactions, collaborations or opportunities in furtherance of our strategic plan. In addition, such activism could make it more difficult to attract and retain qualified personnel, customers and business partners, which could disrupt the growth of the market for OVA1, delay the development and commercialization of new tests and further adversely affect the trading price of our common stock and increase its volatility. In addition, the activists may have little or no experience in the diagnostics industry or may seek to elect members to our Board of Directors with little or no experience in the diagnostics industry who may have a specific agenda different and apart from the majority of our stockholders.

Table of Contents

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

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

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

As of March 31, 2013, we had 15,213,246 shares of our common stock outstanding and 48,329 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 1,054,916 shares of our common stock that were subject to outstanding options. In addition, as of March 31, 2013, warrants to purchase 63,000 shares of our common stock were outstanding at an exercise price of $2.78 per share. On May 13, 2013, we issued an additional 8,000,000 shares of common stock and warrants to purchase an additional 12,500,000 shares of common stock.

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

If an increase to the 2010 Stock Incentive Plan is not approved by stockholders, the limited number of shares we could issue may impact our ability to attract, retain and motivate key personnel, including our chief executive officer.

We have a limited number of shares available under the 2010 Stock Incentive Plan (the 2010 Plan). A proposal to increase the number of shares available for issuance under the 2010 Plan was not approved by stockholders at the annual meeting held on March 21, 2013. We intend to again seek stockholder approval of an increase in the number of shares available for issuance under the 2010 Plan, but there can be no assurances that such increase will be approved. We have historically used stock options as a significant component of our employee compensation program in order to align employees interests with the interests of our stockholders, encourage employee retention, and provide competitive compensation packages. Our chief executive officer was hired in March 2013 and was awarded a stock option grant which is subject to shareholder approval of a 2010 Stock Incentive Plan amendment. If we are unable to increase the number of shares available under the 2010 Plan, our ability to offer attractive equity incentive awards in the future may be limited or nonexistent and may make it more difficult for us to attract, retain and motivate key personnel, including our chief executive officer.

Table of Contents

ITEM 6. EXHIBITS

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

Exhibit		Incorporated by Reference				
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
2.1	Findings of Fact, Conclusions of Law and Order Confirming Debtor s (Vermillion Inc. s) Second Amended Plan of Reorganization Under Chapter 11 of the Bankruptcy Code dated January 7, 2010	8-K	000-31617	2.1	January 12, 2010	
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	Third Amended and Restated Bylaws of Vermillion, Inc., as amended effective May 15, 2012	10-K	001-34810	3.2	March 1, 2013	
4.1	Form of Vermillion, Inc. s (formerly Ciphergen Biosystems, Inc.) Common Stock Certificate	S-1/A	333-32812	4.1	August 24, 2000	
4.2	Preferred Shares Rights Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Continental Stock Transfer & Trust Company dated March 20, 2002	8-A	000-31617	4.2	March 21, 2002	
4.3	Amendment to Rights Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Wells Fargo Bank, N.A. dated July 22, 2005	8-K	000-31617	4.4	July 28, 2005	
4.4	Second Amendment to Rights Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Wells Fargo Bank, N.A. dated September 30, 2005	8-K	000-31617	4.5	October 4, 2005	
4.5	Third Amendment to Rights Agreement between Vermillion, Inc. and Wells Fargo Bank, N.A., dated September 11, 2007	8-K	000-31617	10.1	September 12, 2007	
10.1	Employment Agreement between Vermillion, Inc. and Thomas McLain effective March 18, 2013 #	8-K	001-34810	10.1	March 13, 2013	
10.2	Consulting Agreement between Vermillion, Inc. and Bruce A. Huebner, dated as of March 18, 2013	8-K	001-34810	10.1	March 20, 2013	
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					ü

Table of Contents

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	(1)
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
# Indicates management contract or compensatory plan.

Table of Contents

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 15, 2013

/s/ Thomas H. McLain
Thomas H. McLain

President and Chief Executive Officer

(Principal Executive Officer)

Date: May 15, 2013

/s/ Eric J. Schoen
Eric J. Schoen

Chief Accounting Officer

(Principal Financial Officer)