

VERMILLION, INC.
Form 10-Q
November 12, 2010
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
For the quarterly period ended September 30, 2010.

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)

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Delaware
(State or other jurisdiction of

33-0595156
(I.R.S. Employer

incorporation or organization)

Identification No.)

12117 Bee Caves Road, Building Two, Suite 100, Austin, Texas
(Address of principal executive offices)

78738
(Zip Code)

Registrant's telephone number, including area code: (512) 519-0400

Former name, former address and former fiscal year, if changed since last report: Not applicable

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

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

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☒

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

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

As of September 30, 2010, the Registrant had 10,416,085 shares of common stock, par value \$0.001 per share, outstanding.

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Vermillion, Inc.

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Vermillion, OVA1, and OvaCalc are trademarks of Vermillion, Inc. *ProteinChip* is a registered trademark of Bio-Rad Laboratories, Inc. *BioSeptra* is a registered trademark of Pall Corporation.

Table of Contents**PART I - FINANCIAL INFORMATION****ITEM 1. UNAUDITED FINANCIAL STATEMENTS****Vermillion, Inc.****Consolidated Balance Sheets****(Amounts in Thousands, Except Share and Par Share Amounts)****(Unaudited)**

	September 30, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,292	\$ 3,440
Accounts receivable	261	
Prepaid expenses and other current assets	605	454
Total current assets	26,158	3,894
Property and equipment, net	197	189
Long-term investments, at fair value		526
Other assets	12	
Total assets	\$ 26,367	\$ 4,609
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,105	\$ 2,227
Accrued liabilities	3,095	1,903
Accrued incentive plan with related parties	2,595	
Debtor-in-possession loan with related party		400
Convertible senior notes	5,000	
Deferred revenue	1,344	
Total current liabilities	13,139	4,530
Long-term debt owed to related party	7,000	10,000
Warrant liability	304	5,659
Long-term deferred revenue	1,133	
Liabilities subject to compromise		11,737
Other liabilities	311	
Total liabilities	21,887	31,926
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2010 and December 31, 2009, respectively		

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Common stock, \$0.001 par value, 150,000,000 shares authorized at September 30, 2010 and December 31, 2009; 10,416,085 and 7,918,705 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively			10	8
Additional paid-in capital		299,124		252,196
Accumulated deficit		(294,495)		(279,475)
Accumulated other comprehensive loss		(159)		(46)
Total stockholders' equity (deficit)		4,480		(27,317)
Total liabilities and stockholders' equity	\$	26,367	\$	4,609

See accompanying notes to the consolidated financial statements.

Table of Contents**Vermillion, Inc.****Consolidated Statements of Operations****(Amounts in Thousands, Except Share and Per Share Amounts)****(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenue:				
Product revenue	\$ 114	\$	\$ 159	\$
License revenue	299		671	
 Total revenue	 413		 830	
Cost of sales:				
Product	13		25	
 Total cost of sales	 13		 25	
 Gross margin	 400		 805	
Operating expenses:				
Research and development ⁽¹⁾	1,111	382	2,797	1,515
Sales and marketing ⁽²⁾	1,025	7	1,751	420
General and administrative ⁽³⁾	1,864	303	6,604	1,928
 Total operating expenses	 4,000	 692	 11,152	 3,863
 Loss from operations	 (3,600)	 (692)	 (10,347)	 (3,863)
Interest income	12	6	25	21
Interest expense	(117)	(434)	(375)	(1,375)
Change in fair value and gain from exercise of warrants, net	980	(9,494)	4,427	(9,473)
Reorganization items	(44)	(398)	(1,641)	(935)
Reorganization items - related party incentive plan			(6,932)	
Debt conversion costs			(141)	
Other income (expense), net	33	(3)	(36)	13
 Loss before income taxes	 (2,736)	 (11,015)	 (15,020)	 (15,612)
Income tax expense				(11)
 Net loss	 \$ (2,736)	 \$ (11,015)	 \$ (15,020)	 \$ (15,623)
 Loss per share - basic and diluted	 \$ (0.26)	 \$ (1.72)	 \$ (1.45)	 \$ (2.45)
 Weighted average common shares used to compute basic and diluted net loss per common share	 10,495,324	 6,394,119	 10,345,995	 6,387,354

Non-cash stock-based compensation expense included in operating expenses:

(1)	Research and development	\$	283	\$	62	\$	788	\$	90
(2)	Sales and marketing		26		5		51		15
(3)	General and administrative		929		76		2,547		240
		\$	1,238	\$	143	\$	3,386	\$	345

See accompanying notes to the consolidated financial statements.

Table of Contents**Vermillion, Inc.****Consolidated Statements of Cash Flows****(Amounts in Thousands)****(Unaudited)**

	Nine Months Ended September 30,	
	2010	2009
Cash flows from operating activities:		
Net loss	\$ (15,020)	\$ (15,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in warrant value and gain from warrant exercise, net	(4,427)	9,473
Accrued incentive plan with related parties	4,141	
Non-cash license revenue	(671)	
Depreciation and amortization	103	270
Debt conversion costs	141	
Loss on sale and disposal of property and equipment	54	(2)
Realized gain on sale of investments	(58)	
Stock-based compensation expense	1,177	345
Amortization of debt discount		45
Amortization of debt issuance costs		9
Write-off of debt issuance costs and discounts related to debt subject to compromise		93
Changes in operating assets and liabilities:		
Accounts receivable	(261)	31
Prepaid expenses and other assets	(163)	11
Accounts payable, accrued liabilities and other liabilities	191	3,028
Deferred revenue	148	
Reorganization Items	(3,859)	
Net cash used in operating activities	(18,504)	(2,320)
Cash flows provided by investing activities:		
Purchase of property and equipment	(170)	
Proceeds from certificate of deposit pledged as collateral on letter of credit		40
Proceeds from sale of investments	465	
Proceeds from sale of property and equipment	5	2
Net cash provided by investing activities	300	42
Cash flows provided by financing activities:		
Principal repayment of debtor-in-possession loan financing with related party	(400)	
Principal repayment of 4.50% convertible senior notes	(2,195)	
Proceeds from private placement offering of common stock, net of issuance costs	42,782	
Proceeds from issuance of common stock from exercise of stock options	42	
Proceeds from stock warrant exercises, net of issuance costs	(133)	1,275
Issuance costs related to conversion of convertible senior notes	(46)	
Net cash provided by financing activities	40,050	1,275
Effect of exchange rate changes on cash and cash equivalents	6	(1)
Net increase (decrease) in cash and cash equivalents	21,852	(1,004)

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Cash and cash equivalents, beginning of period	3,440	2,464
Cash and cash equivalents, end of period	\$ 25,292	\$ 1,460

Supplemental disclosure of cash flow information:

Cash paid during the period for:		
Interest	\$ 1,341	\$ 67
Income taxes		10
Noncash investing and financing activities:		
Principal reduction from conversion of senior convertible notes	\$ (170)	\$
Principal reduction from forgiveness of Quest secured line of credit	(3,000)	
Issuance of common stock from warrant exercise	1,059	2,050
Issuance of common stock from conversion of principal and interest for senior convertible notes	504	
Unrealized loss (gain) on investments		(123)
Cumulative effect of change in accounting principle - warrant liability		(21)
Cumulative effect of change in accounting principle - unrealized loss on investments		66

See accompanying notes to the consolidated financial statements.

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Vermillion, Inc.

Notes to Consolidated Financial Statements

(Unaudited)

1. ORGANIZATION, BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING AND REPORTING POLICIES

Organization

In this Quarterly Report on Form 10-Q, unless the context otherwise requires, Vermillion, Inc., a Delaware corporation, and its wholly-owned subsidiaries, are referred to as we, the Company or Vermillion.

We discover, develop and commercialize diagnostics tests in the fields of oncology, hematology, cardiology and women's health. On March 9, 2010, the Company commercially launched its OVA1 ovarian tumor triage test (the OVA1 Test) and on September 20, 2010 the OVA1 Test was CE marked, a requirement for marketing the test in the European Union.

We have incurred significant net losses and negative cash flows from operations since inception. We currently generate revenue solely through sales and collaborations associated with the OVA1 Test. Our ability to achieve our business objectives is dependent upon, among other things, generating sufficient revenue in excess of costs or raising additional capital. We may seek to raise additional funding from various possible sources, including the public equity market, private financings, sales of assets, collaborative arrangements and debt.

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, 2009, 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, 2009, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC) on May 20, 2010.

The Financial Accounting Standards Board's (FASB) Accounting Standards Codification (ASC or Codification) 852 Reorganizations applied to the Company's financial statements while we operated under the provisions of Chapter 11 of the United States Bankruptcy Code (Chapter 11). ASC 852 does not change the application of GAAP in the preparation of financial statements. However, for periods including and subsequent to the filing of the Chapter 11 petition ASC 852 does require that the financial statements distinguish transactions and events that are directly associated with the reorganization from the ongoing operations of the business. Accordingly, certain expenses that were realized or incurred during the Chapter 11 proceedings have been classified as reorganization items on the accompanying consolidated statements of operations. In addition, pre-petition obligations that were impacted by the Plan of Reorganization approved by the Bankruptcy Court on January 7, 2010 (the Plan of Reorganization) were classified as liabilities subject to compromise on the consolidated balance sheet as of December 31, 2009. Upon emergence from bankruptcy, we reclassified the pre-petition obligations back to accounts payable, accrued liabilities and convertible senior notes as is reflected on the consolidated balance sheet at September 30, 2010.

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.

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Vermillion, Inc.

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

Significant Accounting and Reporting Policies

The Company's significant accounting policies are disclosed in its Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on May 20, 2010, and have not changed significantly since May 20, 2010 with exception to the following:

Revenue Recognition

Product Revenue. The Company derives its product revenues from sales of the OVA1 Test. Our product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to meeting all of these revenue recognition criteria for tests performed during the period, we recognize deferred revenue on the consolidated balance sheet.

License Revenue. Under the terms of the secured line of credit with Quest Diagnostics Incorporated (Quest), portions of the borrowed principal amounts may be forgiven upon the Company's achievement of certain milestones relating to the development, regulatory approval and commercialization of certain diagnostic tests (see Note 5). We account for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest receives upon commercialization of an approved diagnostic test. Until we have a meaningful history of product sales that provide a reasonable basis for estimating future product sales, we recognize license revenue straight-line over the 2.5-year period of Quest's sales exclusivity beginning on the OVA1 Test commercialization date of March 9, 2010.

2. CHAPTER 11 BANKRUPTCY

On March 30, 2009, we filed a voluntary petition for relief under Chapter 11 in the United States Bankruptcy Court for the District of Delaware (the Bankruptcy Court). We operated our business and managed our properties as debtors in possession while under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and orders of the Bankruptcy Court. On January 22, 2010, we emerged from bankruptcy.

Financial Statement Presentation

The accompanying consolidated financial statements have been prepared in accordance with ASC 852, and on a going-concern basis, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the ordinary course of business.

Substantially all of our pre-petition debt was in default due to the Bankruptcy Filing. As described below, the accompanying consolidated financial statements present our pre-petition 4.50% Convertible Senior Notes due 2009 (the 4.50% Notes) and 7.00% Convertible Senior Notes due 2011 (the 7.00% Notes) totaling \$7,365,000 as liabilities subject to compromise at December 31, 2009.

Liabilities Subject to Compromise

As required by ASC 852, we recorded liability amounts for the claims that can be reasonably estimated and believe are probable of being allowed by the Bankruptcy Court. Such claims are subject to future adjustments that may result from, among other things, negotiations with creditors, and rejection of executory contracts and unexpired leases. Liabilities subject to compromise may change due to reclassifications, settlements or reorganization activities that give rise to new claims or increases in existing claims. Upon emergence from bankruptcy in January 2010, approved claims were either paid or assumed by the Company at an agreed upon rate. Certain matters are still subject to disputes as noted below under the Plan of Reorganization.

Liabilities subject to compromise in the consolidated balance sheet consisted of the following at December 31, 2009 (in thousands):

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Accounts payable	\$ 1,932
Accrued liabilities	1,696
Payroll and benefits related expenses	744
Convertible senior notes	7,365
Total liabilities subject to compromise	\$ 11,737

Table of Contents**Vermillion, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)*****Reorganization Items***

Professional advisory fees and other costs directly associated with the Company's reorganization are reported separately as reorganization items pursuant to ASC 852. Professional fees include legal fees undertaken as part of the reorganization process. The write-off of debt issuance costs and discounts related to debt generally represent one-time charges. Certain expenses incurred by non-debtors are paid by the Company and are reported as reorganization items. The reorganization items in the consolidated statement of operations for the three and nine months ended September 30, 2010 and 2009 consisted of the following items:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Debtors reorganization items				
Professional fees associated with bankruptcy proceedings	\$ 35	\$ 238	\$ 892	\$ 610
Write-off of debt issuance costs and discounts related to debt subject to compromise				93
DIP financing fees		107		159
Related party incentive plan			6,932	
Debtors reorganization items	35	345	7,824	862
Non-Debtors reorganization items				
Professional fees associated with bankruptcy proceedings	9	53	749	73
Total reorganization items	\$ 44	\$ 398	\$ 8,573	\$ 935

Debtor-In-Possession Credit and Security Agreement with Quest

On October 16, 2009, the Bankruptcy Court gave final approval for us to enter into a Debtor-In-Possession Credit and Security Agreement (the "DIP Loan Agreement") with Quest and to assume under the Bankruptcy Code the strategic alliance agreement with Quest (the "Strategic Alliance Agreement"), and its amendments thereto (the Strategic Alliance Agreement and the July 21, 2008, October 24, 2008 and October 7, 2009, amendments are collectively referred to as the "Amended Strategic Alliance Agreement"). In connection with the assumption of the Amended Strategic Alliance Agreement, we also assumed certain other agreements with Quest related to the Amended Strategic Alliance Agreement, including the pre-petition warrants for the purchase of our common stock. On October 27, 2009, we received \$400,000 under this agreement. On January 22, 2010, we repaid the \$400,000 and interest of \$4,000, which terminated the DIP Loan Agreement. Professional service fees relating to the DIP Loan Agreement were expensed as incurred and classified as reorganization items in the accompanying consolidated statement of operations.

Plan of Reorganization

On January 7, 2010, the Bankruptcy Court issued a confirmation order approving our Plan of Reorganization. The Plan of Reorganization contemplated the reorganization of the Company and the discharge of all outstanding claims against and interests in the Company. Pursuant to the Plan of Reorganization, as confirmed, each holder of an allowed priority claim received cash in an amount equal to such allowed claim. The secured claim arising from the Quest Credit Agreement and the Patent Security Agreement (the "secured line of credit") was reinstated and unimpaired. Holders of the outstanding 4.50% Notes received the payment of \$2,195,000 of principal, the unpaid interest of \$140,000 and 9,044

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shares of common stock in exchange for their claims. \$5,000,000 in principal of the outstanding 7.00% Notes was reinstated and is due September 2011. Holders of unpaid interest on previously converted 7.00% Notes received \$362,000 in cash and 7,239 shares related to the unpaid interest of the 7.00% Notes. All holders of allowed general unsecured claims elected to receive cash and were entitled to be paid in full.

Subsequently on January 22, 2010, the confirmation order issued by the Bankruptcy Court for approving our Plan of Reorganization became final and all conditions precedent to January 22, 2010 were satisfied or waived. Accordingly, we emerged from bankruptcy under Chapter 11 and reinstated our common stock, par value \$0.001. Although we have emerged from bankruptcy, the bankruptcy case will remain open until the following matters are resolved, which includes approval by the Bankruptcy Court:

Molecular Analytical Systems, Inc. Litigation (see Note 6);

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Bio-Rad Laboratories, Inc. Matters (see Note 6);

\$1,000,000 milestone under the Strategic Alliance Agreement with Quest (see Note 5); and

Various pre-petition liability objections.

3. RECENT ACCOUNTING PRONOUNCEMENTS

In October 2009, the FASB issued Accounting Standards Update 2009-13, Revenue Recognition (Topic 605): *Multiple Deliverable Revenue Arrangements A Consensus of the FASB Emerging Issues Task Force*. This update provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. The Company will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. We have not yet determined the impact that this update may have on our consolidated financial statements.

In January 2010, the FASB issued updated guidance related to fair value measurements and disclosures, which requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and to describe the reasons for the transfers. The adoption of the updated guidance did not have a material impact on its consolidated results of operations or financial condition.

4. FAIR VALUE MEASUREMENT AND MARKETABLE SECURITIES

The Company invests in money market funds and has historically invested in both money market funds and auction rate securities. The following is a summary of available-for-sale securities at September 30, 2010 and December 31, 2009:

(in thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
September 30, 2010:				
Money market funds	\$ 24,235	\$	\$	\$ 24,235
	\$ 24,235	\$	\$	\$ 24,235
December 31, 2009:				
Money market funds	\$ 8	\$	\$	\$ 8
Long term investments in auction rate securities	407	119		526
	\$ 415	\$ 119	\$	\$ 534

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As of September 30, 2010, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above was as follows:

(in thousands)	Total Fair Value	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 24,235	\$ 24,235	\$	\$
Total	\$ 24,235	\$ 24,235	\$	\$

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Notes to Consolidated Financial Statements (Continued)

(Unaudited)

At September 30, 2010, the Company's Level 1 financial assets are money market funds.

At December 31, 2009, long-term investments available-for-sale measured at fair value using Level 3 inputs consisted of auction rate securities. The continued failure of auctions and the lack of market activity and liquidity required that these securities be measured using Level 3 inputs. At December 31, 2009, the Company's auction rate securities in credit-linked notes were valued using a single factor Gaussian copula model and market bids received from Deutsche Bank. On July 26, 2010, we sold the auction rate securities investments for total proceeds of \$465,000 and recorded a realized gain on investment of \$58,000.

We measure certain common stock warrants at fair value on a recurring basis (see Note 9). We measure all other financial assets and liabilities at fair value on a nonrecurring basis. We recognize these financial assets and liabilities at fair value when they are deemed to be other-than-temporarily impaired.

5. SECURED LINE OF CREDIT WITH QUEST DIAGNOSTICS INCORPORATED

On July 22, 2005, in connection with the Strategic Alliance Agreement, Quest provided us with a \$10,000,000 secured line of credit, which is collateralized by certain of our intellectual property and may only be used for payment of certain costs and expenses directly related to develop and commercialize up to three diagnostic tests from our product pipeline (the "Strategic Alliance"). Under the terms of this secured line of credit, the interest rate is at the prime rate plus 0.5% and is payable monthly. Upon default on any principal or interest payment, the interest rate is increased to prime plus 2.0%. This secured line of credit also contains provisions for Quest 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 (the "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 and any unpaid interest of this secured line of credit will become due and payable on October 7, 2012.

We achieved the milestone for FDA clearance of the first diagnostic test kit when the OVA1 Test was approved by the FDA in September 2009. While we were under Chapter 11 bankruptcy protection, we had not paid accrued interest on the secured line of credit and were therefore in default. In January 2010, we emerged from bankruptcy and cured the default upon payment of accrued interest, and as a result of the cure, the principal on the secured line of credit was reduced by \$3,000,000 to \$7,000,000. We are in discussions with Quest regarding the achievement of an additional \$1,000,000 forgiveness milestone related to the OVA1 Test under the terms of the Strategic Alliance Agreement.

6. COMMITMENTS AND CONTINGENCIES

Under the terms of a research collaboration agreement with The Johns Hopkins University School of Medicine ("JHU"), we were required to pay JHU \$600,000, \$618,000 and \$637,000 for the years ending December 31, 2008, 2009 and 2010, respectively. In June 2010, the research collaboration agreement was amended by extending the term and reducing the payments to \$300,000 for 2010, \$400,000 for 2011, \$400,000 for

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2012 and \$100,000 for 2013. In conjunction with the amendment, JHU forgave the previously outstanding amounts we owed of \$623,000, which we recognize as a reduction to research and development expenses straight line over the term of the amended agreement. Collaboration costs under the JHU collaboration were \$68,000 and \$275,000 for the three and nine months ended September 30, 2010, respectively, and \$154,000 and \$462,000 for the three and nine months ended September 30, 2009, respectively. Collaboration costs under the JHU collaboration are included in research and development expenses. In addition, under the terms of the amended research collaboration agreement, we are required to pay the greater of 4% royalties on net sales of diagnostic tests using the assigned patents or annual minimum royalties of \$50,000.

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Vermillion, Inc.

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

In June 2010, the Company entered into noncancelable facility leases for facilities located in Austin, Texas through May 2012 and Mountain View, California through August 2012. The combined annual base rent for these facilities is \$129,000 per year, prorated for partial years. In July 2010, the Company relocated its corporate headquarters from Fremont, CA to Austin, TX. The Fremont, California lease expired in August 2010.

Contingent Liabilities

Molecular Analytical Systems, Inc. Litigation

On July 9, 2007, Molecular Analytical Systems (MAS) filed a lawsuit in the Superior Court of California for the County of Santa Clara naming Vermillion and Bio-Rad Laboratories, Inc. (Bio-Rad) as defendants (the State Court lawsuit). Under the State Court lawsuit, MAS seeks an unspecified amount of damages and alleges, among other things, that Vermillion is in breach of its license agreement with MAS relating to the Company's Surfaced Enhanced Laser Desorption/Ionization (SELDI) technology as a result of Vermillion's entry into a sublicense agreement with Bio-Rad. Vermillion filed a petition to compel arbitration, which was denied in the trial court. Vermillion then filed its general denial and affirmative defenses on April 1, 2008. The Company and Bio-Rad thereafter appealed the denial of the motion to compel arbitration, which appeal had the effect of staying the State Court lawsuit, which stay was further extended in both the state trial and appellate courts when the Company filed on March 30, 2009, a Voluntary Petition for Relief under Chapter 11 in the Bankruptcy Court. MAS filed a proof of claim on June 30, 2009, in connection with the Company's Chapter 11 bankruptcy proceedings. The proof of claim mirrored the MAS lawsuit and asserted that the Company breached the Exclusive License Agreement by transferring certain technologies to Bio-Rad without obtaining MAS's consent. MAS listed the value of its claim as in excess of \$5,000,000. On December 28, 2009, the Company objected to MAS's Proof of Claim in the Bankruptcy Court. On January 7, 2010, the Bankruptcy Court confirmed the Company's Plan of Reorganization. Per the Court's order confirming the Plan, the Company's bankruptcy case will be closed when, along with other requirements, a final, non-appealable judgment is entered on MAS's claims. After the Plan of Reorganization was confirmed, MAS filed a motion with the Bankruptcy Court asking it to abstain from hearing its proof of claim and asked the Bankruptcy Court to grant relief from stay so that MAS could proceed with the State Court lawsuit in California. The Bankruptcy Court granted that motion on March 15, 2010. Thereafter, the California Court of Appeal set oral argument on the Company's appeal of the trial court order denying the Company's motion to compel arbitration for June 17, 2010. The California Court of Appeals overturned the Superior Court's decision in an opinion dated July 9, 2010, and ordered that the dispute be arbitrated before the Judicial Arbitration and Mediation Service (JAMS). MAS filed its demand for arbitration on September 15, 2010. The demand did not include any additional detail regarding MAS's claims, and instead submitted the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. JAMS has not yet set a schedule for resolution of MAS's claims, and management cannot predict the ultimate outcome of this matter at this time.

Bio-Rad Laboratories, Inc. Matters

On November 13, 2006, the Company completed the sale of assets and liabilities of its protein research products and collaborative services business (the Instrument Business Sale) to Bio-Rad. The Instrument Business Sale included the Company's SELDI technology, ProteinChip arrays and accompanying software. Pursuant to the terms of the sales agreement, the total sales price was \$20,000,000, of which \$16,000,000 was paid by Bio-Rad to the Company at the closing of the transaction on November 13, 2006. A total of \$4,000,000 was held back from the sales proceeds contingent upon the Company meeting certain obligations, of which \$2,000,000 was subsequently paid to the Company in fiscal 2007 upon the issuance by the United States Patent and Trademark Office of a reexamination certificate for United States Patent No. 6,734,022. From the amounts held back, the remaining \$2,000,000, subject to certain adjustments, is being held in escrow to serve as security for the Company to fulfill certain obligations.

In connection with the Instrument Business Sale, the Company entered into a letter agreement with Bio-Rad pursuant to which the Company agreed to indemnify Bio-Rad and its subsidiaries with respect to certain payments made by Bio-Rad in connection with the termination of employees of its former subsidiary in the United Kingdom in the six-month period immediately following the Instrument Business Sale. On

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May 4, 2007, Bio-Rad delivered a claim for indemnification under the agreement for \$307,000, which was paid out of \$2,000,000 held in escrow. In August 2009, Bio-Rad also filed a proof of claim in the bankruptcy case for indemnification of the MAS lawsuit. Management is disputing the claim and cannot predict the ultimate outcome of this matter at this time.

In connection with the Instrument Business Sale, the Company also entered into a manufacture and supply agreement with Bio-Rad on November 13, 2006, whereby we agreed to purchase ProteinChip Systems and ProteinChip Arrays (collectively, the Research Tools Products) from Bio-Rad. Under the terms of the manufacture and supply agreement, we agreed to provide Bio-Rad quarterly, non-binding, twelve-month rolling forecasts setting forth our anticipated needs for Research Tools Products over the

Table of Contents**Vermillion, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)**

forecast period. We were permitted to provide revised forecasts as necessary to reflect changes in demand for the products, and Bio-Rad was required to use commercially reasonable efforts to supply amounts in excess of the applicable forecast. Either party was permitted to terminate the agreement for convenience upon 180 days prior written notice, or upon default if the other party failed to cure such default within 30 days after notice thereof. In a letter from the Company to Bio-Rad dated May 2, 2008, we exercised our right to terminate the November 13, 2006 manufacture and supply agreement for convenience upon 180 days written notice. Consequently, termination of the agreement became effective on October 29, 2008. In October 2009, Bio-Rad filed a proof of claim in our bankruptcy case based on certain contract claims for approximately \$1,000,000. We are attempting to resolve the contract claims and have accrued for this contingency within general and administrative expense at September 30, 2010 and December 31, 2009. Management cannot predict the ultimate outcome of this matter at this time.

In addition, from time to time, the Company is 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.

7. ACCUMULATED OTHER COMPREHENSIVE LOSS

The components of accumulated other comprehensive loss as of September 30, 2010 and 2009 were as follows:

(in thousands)	September 30,	
	2010	2009
Net unrealized gain on long-term investments available-for-sale	\$	\$ 57
Cumulative translation adjustment	(159)	(163)
Accumulated other comprehensive loss	\$ (159)	\$ (106)

8. EMPLOYEE BENEFITS PLANS***2010 Stock Option Plan***

On February 8, 2010, our Board of Directors approved the Vermillion, Inc. 2010 Stock Incentive Plan (the 2010 Plan). The 2010 Plan will be 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.

Stock-Based Compensation***Employee Stock-based Compensation Expense***

The Company granted options to purchase up to 49,500 and 195,500 shares of common stock with an average exercise price of \$7.81 and \$21.59 during the three and nine months ended September 30, 2010, respectively. No options were granted during the three and nine months ended September 30, 2009. The fair value of the stock options granted was valued on the date of grant using the Black-Scholes valuation model using the following average assumptions:

	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2010
Dividend yield	0%	0%
Volatility	81%	82%
Risk-free interest rate	1.97%	2.37%
Expected lives (years)	5.7	5.6
Weighted average fair value	\$ 5.34	\$ 14.95

Table of Contents**Vermillion, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)**

The allocation of employee stock-based compensation expense by functional area for the three and nine months ended September 30, 2010 and 2009, was as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	\$ 283	\$ 4	\$ 750	\$ 32
Sales and marketing	26		46	10
General and administrative	929	58	2,447	222
Total	\$ 1,238	\$ 62	\$ 3,243	\$ 264

Non-employee Stock-based Compensation Expense

We recognize stock-based compensation expense related to stock options granted to non-employees as the stock options are earned. As part of the bankruptcy case, certain former employees were converted into consultants whereby their existing stock options continued to vest, under the original terms of their stock option grants, as they provided consulting services to the Company. We amortize the values attributable to these options over the service period. The unvested portion of these options was re-measured at each vesting date. We believe that the fair value of the stock options is more reliably measurable than the fair value of the services received. There were no remaining non-employee stock options outstanding at September 30, 2010. We revalued the fair value of the stock options granted at each reporting date using the Black-Scholes valuation model using the following average assumptions:

	Nine Months Ended September 30, 2010
Dividend yield	0%
Volatility	82%
Risk-free interest rate	3.19%
Expected lives (years)	7.81
Weighted average fair value	\$ 14.44

The stock-based compensation expense will fluctuate as the fair market value of the common stock fluctuates. In connection with stock options relating to non-employees, we recorded non-employee stock-based compensation allocated by functional area for the three and nine months ended September 30, 2010, as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009

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Research and development	\$	\$ 58	\$ 38	\$ 58
Sales and marketing		5	5	5
General and administrative		18	100	18
Total	\$	\$ 81	\$ 143	\$ 81

9. COMMON STOCK

January 2010 Private Placement

On January 7, 2010, in connection with the Plan of Reorganization, we completed a private placement sale of 2,327,869 shares of our common stock at a price of \$18.4932 per share to a group of new and existing investors for \$43,050,000 in gross proceeds (net proceeds of \$42,782,000), of which \$42,780,000 was recorded as additional paid-in capital.

Table of Contents**Vermillion, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)****Common Stock Warrants**

At September 30, 2010 and December 31, 2009, the Company had warrants outstanding to purchase 195,012 shares of common stock and 273,467 shares of common stock, respectively, which are subject to fair value measurement on a recurring basis. The fair value of these common stock warrants on September 30, 2010 was determined using a Black Scholes valuation model with the following Level 3 inputs:

	September 30, 2010
Dividend yield	0%
Volatility	81%
Risk-free interest rate	0.40%
Expected lives (years)	1.92
Weighted average fair value	\$ 1.56

As a result of warrant exercises, we recognized total gains of none and \$223,000 for the three and nine months ended September 30, 2010, respectively, and recognized a gain of \$5,676,000 for both the three and nine months ended September 30, 2009. The following table is a reconciliation of the warrant liability measured at fair value using Level 3 inputs for the three and nine months ended September 30, 2010 and 2009:

(in thousands)	Three Months Ended September 30, 2010	September 30, 2009	Nine Months Ended September 30, 2010	September 30, 2009
Balance at beginning of period	\$ 1,284	\$	\$ 5,659	\$
Cumulative effect of change in accounting principle for common stock warrants				21
Change in fair value of common stock warrants	(980)	15,170	(4,204)	15,149
Reclassification of warrant fair value to equity upon exercise and issuance of common stock		(7,760)	(1,151)	(7,760)
Balance at end of period	\$ 304	\$ 7,410	\$ 304	\$ 7,410

The following table sets forth the Company's financial liabilities, related to common stock warrants issued in the August 29, 2007 private placement, subject to fair value measurements as of September 30, 2010:

(in thousands)	Total Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
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			Assets (Level 1)		
Liabilities:					
Common stock warrants	\$	304	\$	\$	\$ 304

10. 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 1,630,095 and 2,655,480 potential common shares as of September 30, 2010 and 2009, respectively, that are antidilutive. Potential common shares include common shares issuable upon conversion of all convertible senior notes, common stock issuable under the Company's 2000 Employee Stock Purchase Plan, incremental shares of common stock issuable upon the exercise of outstanding stock options, common stock warrants and restricted stock awards.

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Vermillion, Inc.

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

11. RELATED PARTY TRANSACTIONS

Consulting Agreement

On March 26, 2009, we entered into a consulting agreement with our former Chief Executive Officer and current Director. For the three months ended September 30, 2010 and 2009, we incurred none and \$40,000, respectively, in general and administrative expenses under the consultant arrangement. For the nine months ended September 30, 2010 and 2009, we incurred \$24,000 and \$95,000 in general and administrative expenses under the consulting arrangement. On February 1, 2010, this consulting agreement was terminated when we re-hired our Chief Executive Officer.

On September 14, 2009, we entered into a consulting agreement with our former Vice President and Chief Science Officer. For the three months ended September 30, 2010 and 2009, we incurred no expenses under the consulting arrangement. For the nine months ended September 30, 2010 and 2009, we incurred \$14,272 and none in research and development expenses under the consulting arrangement, respectively. On February 1, 2010, this consulting agreement was terminated when we re-hired our Senior Vice President and Chief Science Officer.

Debtors Incentive Plan

In connection with the Bankruptcy Filing, on April 21, 2009, the Company filed the Debtors Motion for Entry of an Order Approving the Debtors Incentive Plan (the Incentive Plan) and Authorizing Payments thereunder pursuant to §§ 363(b) and 503(b) of the Bankruptcy Code (the Incentive Plan Motion) which sought to provide proper incentives to the Directors (Gail Page, John Hamilton and James Burns, collectively, the Directors) to help achieve a successful restructuring of the Company. Under the final terms of the Incentive Plan, the Company was directed to distribute an aggregate of \$5,000,000 in cash and 302,541 shares of restricted stock having a fair value of \$6,626,000 in Incentive Plan Payments to the Directors. All such restricted stock is to be distributed, with 1/24th of it to vest on each monthly anniversary of the vesting commencement date, June 22, 2009. The liability was accounted for upon the occurrence of the qualified transaction on January 7, 2010 when the Bankruptcy Court issued a confirmation order approving the Company's Reorganization Plan. Accordingly, the Company recorded a charge of \$828,000 and \$9,141,000 for the three and nine months ended September 30, 2010, respectively, and will record additional charges totaling \$2,485,000 through June 2011 as the underlying restricted stock vests. As of September 30, 2010, the Company incurred \$9,141,000 under the terms of the Incentive Plan, of which \$6,932,000 was recorded in Reorganization Items for the period prior to emerging from bankruptcy and \$2,209,000 was recorded in general and administrative expenses for the period subsequent to emerging from bankruptcy. In April 2010, the Company distributed an aggregate of \$5,000,000 in cash to the Directors. The Company distributed 70,590 and 10,086 shares of common stock to the Directors under the Incentive Plan in September and October 2010, respectively.

12. SUBSEQUENT EVENTS

Qualifying Therapeutic Discovery Project Program

In November 2010, the Company received notice of an award of two grants for the aggregate sum of \$489,000 under the Internal Revenue Service Qualifying Therapeutic Discovery Projects Grant Program for the OVA2™ and PAD programs. The grant relates to 2010 expenditures and was awarded to therapeutic discovery projects that show a reasonable potential to result in new therapies that treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions.

Quest Strategic Alliance Agreement Amendment

On November 10, 2010, we entered into Amendment No. 4 (the Amendment) to the Strategic Alliance Agreement with Quest. Pursuant to the Amendment, Quest will have the exclusive right to commercialize the OVA1 Test for a certain period of time as specified in the Amendment.

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The Amendment also establishes royalties, fees, and other payments related to the performance of the OVA1 Test. Quest will pay the Company a fixed payment of \$50 per OVA1 Test performed, as well as 33% of its gross margin, as the term is defined in the Amendment.

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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. The Company claims the protection of such safe harbor, and disclaims any intent or obligation to update any forward-looking statement. You can identify these statements by forward-looking words such as may, will, expect, intend, anticipate, believe, estimate, plan, could, should and continue or similar words. These forward-looking statements may also use different phrases. The Company has based these forward-looking statements on management's (we, us or our) current expectations and projections about future events. Examples of forward-looking statements include the following statements:

projections of our future revenue, results of operations and financial condition;

anticipated efficacy of our products, product development activities and product innovations;

competition and consolidation in the markets in which we compete;

existing and future collaborations and partnerships;

the utility of biomarker discoveries;

our belief that biomarker discoveries may have diagnostic and/or therapeutic utility;

our plans to develop and commercialize diagnostic tests through our strategic alliance with Quest;

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 the OVA1 Test;

our ability to obtain reimbursement for our diagnostic tests, including the OVA1 Test;

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

market risk of our investments.

These 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 new diagnostic products; our ability to manage the Company's operating expenses and cash resources that is consistent 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 our OVA1 Test 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 commercialize our products; our ability to obtain any regulatory approval for our future diagnostic products; 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 the Company's forward-looking statements.

Overview

Vermillion was originally incorporated in California on December 9, 1993, under the name Abiotic Systems. In March 1995, Abiotic Systems changed its corporate name to CIPHERGEN Biosystems, Inc., and subsequently on June 21, 2000, it reincorporated in Delaware. Under the name CIPHERGEN Biosystems, Inc., the Company had its initial public offering on September 28, 2000. On November 13, 2006, the Company sold the assets and liabilities of its protein research products and collaborative services business to Bio-Rad, which allowed it to focus on the development of its diagnostics tests. On August 21, 2007, CIPHERGEN Biosystems, Inc. changed its corporate name to Vermillion, Inc.

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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 guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, or to assist in the selection of therapy. A distinctive feature of our approach is to combine multiple markers into a single, reportable index score that has higher diagnostic accuracy than its constituents. We concentrate our development of novel diagnostic tests in the fields of oncology, hematology, cardiology 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 others through collaborations with leading academic and research institutions.

Our lead product, the OVA1 Test, was cleared by the FDA on September 11, 2009. The OVA1 Test 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 the OVA1 Test, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. The OVA1 Test is a qualitative serum test that utilizes five well-established biomarkers and proprietary FDA-cleared software to determine the likelihood of malignancy in women with a pelvic mass for whom surgery is planned. The OVA1 Test was developed through large pre-clinical studies in collaboration with numerous academic medical centers encompassing over 2,500 clinical samples. The OVA1 Test 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 the OVA1 Test, in conjunction with clinical evaluation, was able to identify 91.7% of the malignant ovarian tumors and to rule out malignancy (negative predictive value, or NPV) with 93.2% certainty.

In addition to the OVA1 Test, we have development programs in other clinical aspects of ovarian cancer as well as in peripheral arterial disease (PAD). In the field of PAD, 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 PAD. We have initiated an intended-use study to validate a multi-marker algorithm for the assessment of individuals at risk for PAD.

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 Research Foundation; Stanford University; and the University of Kentucky.

On July 22, 2005, we entered into the Strategic Alliance Agreement with Quest. The Strategic Alliance Agreement was set to expire on the earlier of (i) the three-year anniversary of the agreement, which was July 22, 2008, and (ii) the date on which Quest commercializes three diagnostic tests. On July 21, 2008, the Strategic Alliance Agreement was amended to extend the term of the agreement to end on the earlier of (i) September 1, 2008 and (ii) the date on which Quest commercializes three diagnostic tests. On October 24, 2008, the Strategic Alliance Agreement was amended to extend the term of the agreement to end on the earlier of (i) September 1, 2009 and (ii) the date on which Quest makes its third development election. Subsequently on October 7, 2009, the Strategic Alliance Agreement was amended to extend the term of the agreement to end on the earlier of (i) October 7, 2012 and (ii) the date on which Quest makes its third development election. To date, Quest has selected only two diagnostic tests, which are the PAD blood test (VASCLIR) and the OVA1 Test, to commercialize. We achieved the milestone provision in the secured line of credit agreement with Quest for FDA clearance of the first diagnostic test kit when the OVA1 Test was cleared by the FDA in September 2009. While we were under Chapter 11 bankruptcy protection, we had not paid accrued interest on the secured line of credit and were therefore in default. In January 2010, we emerged from bankruptcy and cured the default upon payment of accrued interest, and as a result of the cure, the principal on the secured line of credit was reduced by \$3,000,000 to \$7,000,000. We are in discussions with Quest regarding the achievement of an additional \$1,000,000 forgiveness milestone related to the OVA1 Test under the terms of the Strategic Alliance Agreement.

On March 30, 2009, we filed a voluntary petition for relief under Chapter 11 in the Bankruptcy Court. Subsequently, on January 22, 2010, the confirmation order issued by the Bankruptcy Court approving our Second Amended Plan of Reorganization under Chapter 11 dated January 5, 2010, became final and all conditions precedent to January 22, 2010, were satisfied or waived. Accordingly, we emerged from bankruptcy under Chapter 11 on January 22, 2010.

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The OVA1 Test was launched on March 9, 2010 by Quest under the terms of the Strategic Alliance Agreement at a list price of \$650.00 for each OVA1 Test. On March 11, 2010, the Medicare contractor Highmark Medicare Services announced that it would cover the OVA1 Test in its reimbursement program. On May 10, 2010, Quest notified Vermillion that Highmark Medicare Services is adjudicating to Quest the OVA1 Test claims in the amount of \$516.25 for each OVA1 Test. We estimate approximately 3,220 OVA1 Tests had been performed as of September 30, 2010. We have recognized product revenue for 1,592 of these tests. The remaining 1,628 performed tests have been recorded as deferred revenue on the consolidated balance sheet. It will not be easy for us to estimate revenues from Quest during the early period of the OVA1 Test's commercial availability. As we enhance our ability to estimate reimbursements, we will be in a position to recognize revenues in better alignment with the actual performance of the test.

On July 6, 2010, we announced that The NASDAQ Stock Market LLC approved our application for the relisting of our common stock on The NASDAQ Global Market. The Company's shares began trading on The NASDAQ Global Market upon market open on Tuesday, July 6, 2010 under the symbol VRML.

On July 23, 2010, we announced the relocation of our corporate headquarters from Fremont, California to Austin, Texas. We will continue to operate research and development, regulatory and quality operations in California. All other functions will be conducted at the Austin office.

On September 14, 2010, we announced that the United States Patent and Trademark Office issued to us a notice of allowance for a patent entitled B2-microglobulin as a biomarker for peripheral artery disease. The patent claims are directed to biomarker combinations that include B2-microglobulin for the diagnosis and management of PAD and to the measurement of the biomarkers by a variety of methods, including mass spectrometry and immunoassay. The studies underlying the patent were conducted with John P. Cooke, M.D., Ph.D., a Professor and Associate Director of the Stanford Cardiovascular Institute at Stanford University School of Medicine. Dr. Cooke is a founder and Past President of the Society for Vascular Medicine and an author of over 350 scientific articles in vascular medicine and biology.

On September 20, 2010, we announced that the OVA1 Test is now CE marked, a requirement for marketing the test in the European Union. The OVA1 Test has satisfied all certification requirements to complete its declaration of conformity.

On September 29, 2010, we announced the appointment of Ashish Kohli as Vice President of Corporate Strategy. Mr. Kohli will be responsible for Investor Relations, Corporate Strategy and Business Development.

On November 2, 2010, we received notice of an award of two grants for the aggregate sum of \$489,000 under the Internal Revenue Service Qualifying Therapeutic Discovery Projects Grant Program for our OVA2TM and PAD programs. The grant relates to 2010 expenditures and was awarded to therapeutic or diagnostic discovery projects that show a reasonable potential to result in new therapies or diagnostic tests that address areas of unmet medical need or that prevent, detect or treat chronic or acute diseases and conditions.

Critical Accounting Policies and Significant Estimates

The Company has made no significant changes in its critical accounting policies and significant estimates from those disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2009, except as disclosed below:

Revenue Recognition

Product Revenue. The Company derives its product revenues from sales of the OVA1 Test. Our product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to meeting all of these revenue recognition criteria for tests performed during the period, we recognize deferred revenue on the consolidated balance sheet.

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License Revenue. Under the terms of the secured line of credit with Quest, portions of the borrowed principal amounts may be forgiven upon the Company's achievement of certain milestones relating to the development, regulatory approval and commercialization of certain diagnostic tests. The Company accounts for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest receives upon commercialization of an approved diagnostic test. Until we have a meaningful history of product sales that provide a reasonable basis for estimating future product sales, we recognize license revenue straight-line over the 2.5-year period of Quest's sales exclusivity beginning on the OVA1 Test commercialization date of March 9, 2010.

Recent Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update 2009-13, Revenue Recognition (Topic 605): *Multiple Deliverable Revenue Arrangements - A Consensus of the FASB Emerging Issues Task Force*. This update provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. The Company will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. The Company has not determined the impact that this update may have on our consolidated financial statements.

In January 2010, the FASB issued updated guidance related to fair value measurements and disclosures, which requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and to describe the reasons for the transfers. The adoption of the updated guidance did not have a material impact on its consolidated results of operations or financial condition.

Table of Contents*Results of Operations - Three Months Ended September 30, 2010 Compared to Three Months Ended September 30, 2009*

The selected summary financial and operating data of Vermillion for the three months ended September 30, 2010 and 2009, were as follows:

(dollars in thousands)	Three Months Ended September 30,		Increase (Decrease)	
	2010	2009	Amount	%
Revenue:				
Product	\$ 114	\$	\$ 114	
License	299		299	
Total revenue	413		413	
Cost of sales:				
Product	13		13	
Total cost of sales	13		13	
Gross margin	400		400	
Operating expenses:				
Research and development	1,111	382	729	191
Sales and marketing	1,025	7	1,018	14,543
General and administrative	1,864	303	1,561	515
Total operating expenses	4,000	692	3,308	478
Loss from operations	(3,600)	(692)	(2,908)	420
Interest income	12	6	6	100
Interest expense	(117)	(434)	317	(73)
Change in fair value and gain from exercise of warrants, net	980	(9,494)	10,474	(110)
Reorganization items	(44)	(398)	354	(89)
Other income (expense), net	33	(3)	36	(1,200)
Net loss	\$ (2,736)	\$ (11,015)	\$ 8,279	(75)

Product Revenue. Product revenue was \$114,000 for the three months ended September 30, 2010 compared to none for the same period in 2009. The Company recognized 1,250 OVA1 Tests as product revenue for the three months ended September 30, 2010 compared to none for the same period in 2009. As we enhance our ability to estimate reimbursements, we will be in a position to recognize revenues in better alignment with the actual performance of the test.

License Revenue. License revenue was \$299,000 for the three months ended September 30, 2010 compared to none for the same period in 2009. Under the terms of our secured line of credit with Quest, \$3,000,000 principal was forgiven upon the achievement of FDA approval for the OVA1 Test. This amount is recognized as license revenue straight-lined over the 2.5-year period of sales exclusivity Quest received beginning on the OVA1 Test commercialization date of March 9, 2010.

Product Cost of Sales. Product cost of sales was \$13,000 for the three months ended September 30, 2010 compared to none for the same period in 2009.

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, including allocated facility occupancy and information technology costs, 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 increased by \$729,000, or 191%, for the three months ended September 30, 2010 compared to the same period in 2009. This increase included a \$221,000 increase in stock-based compensation, a \$199,000 increase in personnel-related expenses and \$152,000 increase in collaboration costs. The increases were primarily due to an increase in personnel and their related stock options granted after our emergence from bankruptcy. We expect our research and development expenses to increase in future periods due to an increased investment in our ovarian cancer program and our PAD blood test.

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Sales and Marketing Expenses. Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses, including allocated facility occupancy and information technology costs. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding our OVA1 Test. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and health economic publications. Sales and marketing expenses increased by \$1,018,000 for the three months ended September 30, 2010 compared to the same period in 2009. The increase was primarily due to a \$665,000 increase in personnel and personnel-related expenses, reflecting the cost of 15 sales and marketing related personnel in the three months ended September 30, 2010, and a \$240,000 increase in trade show, advertising and marketing expenses related to the commercialization launch of our OVA1 Test. There were no sales and marketing personnel in the three months ended September 30, 2009. We expect sales and marketing expenses to increase in future periods due to our continued efforts to establish adoption of, and reimbursement for, our OVA1 Test.

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, including allocated facility occupancy and information technology costs. The \$1,561,000, or 515%, increase in general and administrative expenses for the three months ended September 30, 2010 was primarily due to a \$853,000 increase in stock-based compensation, a \$151,000 increase in audit and tax related service fees, a \$374,000 increase in personnel-related expenses, partially offset by a \$299,000 decrease in legal expenses. Personnel, audit and tax related expenses increased due to costs to maintain compliance with the periodic reports required by the Securities and Exchange Act of 1934 (the Exchange Act). The Company also incurred \$828,000 for the value of the vested portions of restricted stock under the Incentive Plan during the three months ended September 30, 2010. Stock-based compensation expense included in general and administrative expenses was \$929,000 and \$76,000 for the three months ended September 30, 2010 and 2009, respectively, including the Incentive Plan costs.

Interest Income. Interest income increased by \$6,000, or 100%, for the three months ended September 30, 2010, compared to the same period in 2009.

Interest Expense. Interest expense decreased by \$317,000, or 73%, for the three months ended September 30, 2010, compared to the same period in 2009. Interest expense in both periods consisted largely of interest related to our convertible senior notes and related party long-term debt; however, total debt outstanding at September 30, 2010 was \$12,000,000 compared to \$29,000,000 at September 30, 2009.

Change in fair value and gain from exercise of warrants, net. The increase in change in fair value and gain from exercise of warrants of \$980,000 for the three months ended September 30, 2010 was primarily due to the change in the Company's stock price from June 30, 2010 to September 30, 2010.

Reorganization Items. Reorganization items for the three months ended September 30, 2010 amounted to \$44,000 compared to \$398,000 for the same period in 2009. Reorganization items include professional advisory fees and other costs directly associated with the Company's Chapter 11 bankruptcy activities.

Other Income (Expense), Net. Net other income was \$33,000 for the three months ended September 30, 2010 compared to \$3,000 expense for the same period in 2009. Other income for the three months ended September 30, 2010 included a \$58,000 realized gain on sale of investment.

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The selected summary financial and operating data of Vermillion for the nine months ended September 30, 2010 and 2009, were as follows:

(dollars in thousands)	Nine Months Ended September 30,		Increase (Decrease)	
	2010	2009	Amount	%
Revenue:				
Product	\$ 159	\$	\$ 159	
License	671		671	
Total revenue	830		830	
Cost of sales:				
Product	25		25	
Total cost of sales	25		25	
Gross margin	805		805	
Operating expenses:				
Research and development	2,797	1,515	1,282	85
Sales and marketing	1,751	420	1,331	317
General and administrative	6,604	1,928	4,676	243
Total operating expenses	11,152	3,863	7,289	189
Loss from operations	(10,347)	(3,863)	(6,484)	168
Interest income	25	21	4	19
Interest expense	(375)	(1,375)	1,000	(73)
Change in fair value and gain from exercise of warrants, net	4,427	(9,473)	13,900	(147)
Reorganization items	(1,641)	(935)	(706)	76
Reorganization items - related party incentive plan	(6,932)		(6,932)	
Debt conversion costs	(141)		(141)	
Other income (expense), net	(36)	13	(49)	(377)
Loss before income taxes	(15,020)	(15,612)	592	(4)
Income tax benefit (expense)		(11)	11	(100)
Net loss	\$ (15,020)	\$ (15,623)	\$ 603	(4)

Product Revenue. Product revenue was \$159,000 for the nine months ended September 30, 2010 compared to none for the same period in 2009. The Company recognized 1,592 OVA1 Tests as product revenue for the nine months ended September 30, 2010 compared to none for the same period in 2009. As we enhance our ability to estimate reimbursements, we will be in a position to recognize revenues in better alignment with the actual performance of the test.

License Revenue. License revenue was \$671,000 for the nine months ended September 30, 2010 compared to none for the same period in 2009. Under the terms of our secured line of credit with Quest, \$3,000,000 principal was forgiven upon the achievement of FDA approval for the OVA1 Test. This amount is recognized as license revenue straight-lined over the 2.5-year period of sales exclusivity Quest received beginning on the OVA1 Test commercialization date of March 9, 2010.

Product Cost of Sales. Product cost of sales was \$25,000 for the nine months ended September 30, 2010 compared to none for the same period in 2009.

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Research and Development Expenses. Research and development expenses increased by \$1,282,000, or 85%, for the nine months ended September 30, 2010 compared to the same period in 2009. This increase included a \$698,000 increase in stock-based compensation, a \$298,000 increase in personnel-related expenses due to the increase in headcount after the emergence from bankruptcy, a \$130,000 increase in collaboration costs partially offset by a \$155,000 decrease in depreciation expense. Stock-based compensation expense increased to \$788,000 for the nine months ended September 30, 2010 compared to \$90,000 for the same period in 2009.

Sales and Marketing Expenses. Sales and marketing expenses increased by \$1,331,000, or 317%, for the nine months ended September 30, 2010 compared to the same period in 2009. The increase was primarily due to a \$781,000 increase in personnel and personnel-related expenses, reflecting the addition of fifteen sales and marketing employees in the nine months ended September 30, 2010, and a \$410,000 increase in trade show, advertising and marketing expenses related to the commercialization launch of our OVA1 Test.

General and Administrative Expenses. General and administrative expenses increased by \$4,676,000, or 243%, for the nine months ended September 30, 2010 compared to the same period in 2009. The increase was primarily due to a \$1,028,000 increase in audit and tax related services, a \$1,570,000 increase in legal expenses, a \$349,000 increase in consulting and other outside service expenses, and a \$322,000 increase in personnel-related expenses. Personnel, consulting, legal, audit and tax related expenses increased due to significant efforts to bring current all periodic reports required by the Exchange Act. Stock-based compensation expense was \$338,000 and \$240,000 for the nine months ended September 30, 2010 and 2009, respectively. Under the terms of the Debtor's Incentive Plan, the Company also incurred \$2,209,000 as related party incentive expenses during the nine months ended September 30, 2010 for the value of the vested portions of restricted stock issued.

Interest Income. Interest income increased by \$4,000, or 19%, for the nine months ended September 30, 2010, compared to the same period in 2009.

Interest Expense. Interest expense decreased by \$1,000,000, or 73%, for the nine months ended September 30, 2010, compared to the same period in 2009. Interest expense in both periods consisted largely of interest related to our convertible senior notes and related party long-term debt; however, total debt outstanding at September 30, 2010 was \$12,000,000 compared to \$29,000,000 at September 30, 2009.

Change in fair value and gain from exercise of warrants. The change in fair value and gain from exercise of warrants of \$4,427,000 for the nine months ended September 30, 2010 was primarily due to the change in the Company's stock price at March 31, 2010 to September 30, 2010. Effective January 1, 2009, the adoption of the new accounting guidance resulted in the reclassification of certain outstanding common stock warrants from stockholders' deficit to liability, which further required re-measurement at the end of each reporting period.

Reorganization Items. Reorganization items for the nine months ended September 30, 2010 totaled \$1,641,000 compared to \$935,000 for the same period in 2009. Reorganization items include professional advisory fees and other costs directly associated with the Company's Chapter 11 bankruptcy activities.

Reorganization items - related party incentive plan. Reorganization items for the nine months ended September 30, 2010 amounted to \$6,932,000. The Company paid \$5,000,000 in cash and accrued \$1,932,000 for the value of the vested portions of restricted stock under the Incentive Plan prior to the Company emerging from bankruptcy.

Debt Conversion Costs. Debt conversion costs for the nine months ended September 30, 2010 totaled \$141,000 compared to none for the same period in 2009.

Other Income (Expense), Net. Net other expense was \$36,000 for the nine months ended September 30, 2010 compared to \$13,000 of income for the same period in 2009. Other expense for the nine months ended September 30, 2010 was partially offset by a \$58,000 realized gain on sale of investment.

Income Tax Benefit (Expense). There was no income tax benefit or expense for the nine months ended September 30, 2010 compared to income tax expense of \$11,000 for the same period in 2009. Income tax expense was due to foreign income taxes.

Liquidity and Capital Resources

The Company has experienced significant cumulative operating losses since inception and, as of September 30, 2010, had an accumulated deficit of \$294,495,000.

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On March 9, 2010, we commercially launched our OVA1 Test. We will continue to expend substantial resources in the selling and marketing of the OVA1 Test, researching and developing additional key diagnostic tests, and obtaining FDA clearance and commercializing those products in addition to the OVA1 Test. We will continue to be in an accumulated deficit position unless sufficient revenues can be generated to offset expenses. We believe that our existing cash and cash equivalents will be sufficient to meet our cash requirements for at least the next twelve months.

The successful achievement of our business objectives may require additional financing and therefore, we may need to raise additional capital or incur indebtedness to continue to fund the Company's future operations. We may seek to raise capital through a variety of sources, including:

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. 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 research and development activities or not be able to pay the convertible senior notes. The Company's 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 conversion terms of our convertible debt; and

the insurance payer community's acceptance of and reimbursement for the OVA1 Test.

Cash and cash equivalents as of September 30, 2010 and December 31, 2009, were \$25,292,000 and \$3,440,000, respectively. At September 30, 2010, the working capital was \$13,019,000, and at December 31, 2009, working deficit was \$636,000.

Net cash used in operating activities was \$18,504,000 for the nine months ended September 30, 2010, resulting primarily from operating losses incurred as adjusted for a change in fair value of warrants and warrant exercises of \$4,427,000 and non-cash license revenues of \$671,000, partially offset by \$141,000 debt issuance costs, \$103,000 depreciation and amortization, \$1,177,000 stock-based compensation expense and \$4,141,000 accrued incentive plan with related parties. Net cash used in operating activities also decreased by \$3,944,000 of cash provided by

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changes in operating assets and liabilities mainly driven by the \$3,859,000 reorganization items.

Net cash used in operating activities was \$2,320,000 for the nine months ended September 30, 2009, primarily as a result of the \$15,623,000 net loss reduced by \$10,233,000 of noncash expenses that included the change in fair value and gain from exercise of warrants of \$9,473,000; depreciation and amortization of \$270,000; stock-based compensation expense of \$345,000; and amortization of convertible senior notes discount of \$122,000. Net cash used in operating activities was also offset by \$3,070,000 of cash provided by changes in operating assets and liabilities.

Net cash provided by investing activities was \$300,000 for the nine months ended September 30, 2010, primarily due to the proceeds from sale of investments of \$465,000 partially offset by the purchase of property and equipment for \$170,000. Net cash provided by investing activities was \$42,000 for the nine months ended September 30, 2009, which primarily resulted from proceeds from the maturity of a certificate of deposit pledged as collateral on a letter of credit.

Net cash provided by financing activities was \$40,050,000 for the nine months ended September 30, 2010, which resulted primarily from net proceeds of \$42,782,000 in connection with our January 2010 private placement, offset by \$2,195,000 in repayments of the 4.50% Notes and \$400,000 of the debtor-in-possession financing with Quest. Net cash provided by financing activities was \$1,275,000 for the nine months ended September 30, 2009, which resulted from net proceeds in connection with stock warrant exercises.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Our senior management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15e and 15d-15e under 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 Financial Officer, performed an evaluation of our disclosure controls and procedures as defined under the Exchange Act as of September 30, 2010. Based on this evaluation and the identification of material weakness in our internal control over financial reporting as described below, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2010.

Material Weakness in Internal Control over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Consistent to what was noted in our Annual Report on Form 10-K for the year ended December 31, 2009, as of September 30, 2010, we did not maintain effective controls over financial reporting. Specifically:

Because of the Company filing a voluntary petition for relief under Chapter 11 in the Bankruptcy Court on March 30, 2009, the Company did not maintain sufficient staff with the necessary experience in GAAP to timely perform its controls procedures relating to the accounting and reporting processes. As a result, the Company was not able to timely file its Forms 10-Q and 10-K in accordance with the Exchange Act's rules and regulations. This control deficiency, if not corrected, could result in a material misstatement of the Company's annual or interim consolidated financial statements that would not be prevented or detected on a timely basis. Therefore, management has concluded that this control deficiency constitutes a material weakness.

Management's Plan for Remediation

The Company continues to evaluate its resource requirements to ensure the timely and effective review and management of its accounting and reporting process. On May 17, 2010 and July 26, 2010, the Company hired a Vice President & Chief Financial Officer and Corporate Controller, respectively (collectively as "Financial Officers"), to help remedy the staffing deficiency. The Financial Officers are in the process of evaluating the staffing requirements and will to the extent necessary, hire additional finance and accounting staff to allow for the preparation of financial statements to be in accordance with GAAP, the timely filing of periodic financial reports with the SEC and effective internal control over financial reporting.

Changes in internal controls over financial reporting.

The Company has made the following change in its internal control over financial reporting that has materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting during the three months ended September 30, 2010: as described above, the Company hired a Corporate Controller on July 26, 2010.

Inherent limitations on the controls of financial reporting.

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Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 9, 2007, Molecular Analytical Systems (MAS) filed a lawsuit in the Superior Court of California for the County of Santa Clara naming Vermillion and Bio-Rad Laboratories, Inc. (Bio-Rad) as defendants (the State Court lawsuit). Under the State Court lawsuit, MAS seeks an unspecified amount of damages and alleges, among other things, that Vermillion is in breach of its license agreement with MAS relating to the Company's Surfaced Enhanced Laser Desorption/Ionization (SELDI) technology as a result of Vermillion's entry into a sublicense agreement with Bio-Rad. Vermillion filed a petition to compel arbitration, which was denied in the trial court. Vermillion then filed its general denial and affirmative defenses on April 1, 2008. The Company and Bio-Rad thereafter appealed the denial of the motion to compel arbitration, which appeal had the effect of staying the State Court lawsuit, which stay was further extended in both the state trial and appellate courts when the Company filed on March 30, 2009, a Voluntary Petition for Relief under Chapter 11 in the Bankruptcy Court. MAS filed a proof of claim on June 30, 2009, in connection with the Company's Chapter 11 bankruptcy proceedings. The proof of claim mirrored the MAS lawsuit and asserted that the Company breached the Exclusive License Agreement by transferring certain technologies to Bio-Rad without obtaining MAS's consent. MAS listed the value of its claim as in excess of \$5,000,000. On December 28, 2009, the Company objected to MAS's Proof of Claim in the Bankruptcy Court. On January 7, 2010, the Bankruptcy Court confirmed the Company's Plan of Reorganization. Per the Court's order confirming the Plan, the Company's bankruptcy case will be closed when, along with other requirements, a final, non-appealable judgment is entered on MAS's claims. After the Plan of Reorganization was confirmed, MAS filed a motion with the Bankruptcy Court asking it to abstain from hearing its proof of claim and asked the Bankruptcy Court to grant relief from stay so that MAS could proceed with the State Court lawsuit in California. The Bankruptcy Court granted that motion on March 15, 2010. Thereafter, the California Court of Appeal set oral argument on the Company's appeal of the trial court order denying the Company's motion to compel arbitration for June 17, 2010. The California Court of Appeals overturned the Superior Court's decision in an opinion dated July 9, 2010, and ordered that the dispute be arbitrated before the Judicial Arbitration and Mediation Service (JAMS). MAS filed its demand for arbitration on September 15, 2010. The demand did not include any additional detail regarding MAS's claims, and instead submitted the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. JAMS has not yet set a schedule for resolution of MAS's claims, and management cannot predict the ultimate outcome of this matter at this time.

In addition, from time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We established reserves for specific liabilities in connection with legal actions that it deems 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.

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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, 2009, 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 ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also adversely affect our business.

Risks Related to Vermillion's Emergence from Bankruptcy

We filed a petition for relief under Chapter 11 on March 30, 2009, and, despite having emerged from bankruptcy on January 22, 2010, we continue to be subject to the risks and uncertainties associated with residual Chapter 11 bankruptcy proceedings.

On March 30, 2009, we filed a voluntary petition for relief under Chapter 11 in the Bankruptcy Court, and on January 22, 2010, we emerged from bankruptcy. Because of the residual risks and uncertainties associated with our Chapter 11 bankruptcy proceedings, the ultimate impact of events that may occur in finalizing and closing these proceedings on our business, financial condition and results of operations cannot be accurately predicted or quantified.

Our actual financial results after our emergence from bankruptcy under Chapter 11 may vary significantly from the projections filed with the Bankruptcy Court.

We emerged from bankruptcy under Chapter 11 of the United States Bankruptcy Code on January 22, 2010, pursuant to terms of our Plan of Reorganization approved by the Bankruptcy Court. In connection with the Plan of Reorganization, we were required to prepare projected financial information to demonstrate to the Bankruptcy Court the feasibility of the Plan of Reorganization and our ability to continue operations upon emergence from bankruptcy under Chapter 11. The projected financial information filed with the Bankruptcy Court reflected numerous assumptions concerning anticipated future performance and prevailing and anticipated market and economic conditions, many of which were and continue to be beyond our control and which may not materialize. Projections are inherently subject to uncertainties and to a wide variety of significant business, economic and competitive risks. Our actual results will likely vary from those contemplated by the projected financial information and the variations may be material.

Risks Related to Our Business

We expect to incur a net loss for fiscal 2010. If we are unable to generate significant product revenue, we may never achieve profitability.

We have experienced significant operating losses each year since our inception and we expect to incur a net loss for fiscal year 2010. Our losses have resulted principally from costs incurred in research and development, sales and marketing, litigation, and general and administrative costs associated with our operations.

Our ability to commercialize our potential diagnostic tests is heavily dependent on our strategic alliance with Quest.

On July 22, 2005, Vermillion and Quest entered into a Strategic Alliance Agreement to develop and commercialize up to three diagnostic tests from our product pipeline. The term of the Strategic Alliance Agreement, which is the period we have an obligation to present three diagnostic tests to Quest for potential election, was set to expire on the earlier of (i) the three-year anniversary of the agreement, which was July 22, 2008, and (ii) the date on which Quest commercializes the three diagnostic tests covered by such agreement. On July 21, 2008, Vermillion and Quest amended the Strategic Alliance Agreement to extend the term of the agreement to end on the earlier of (i) September 1, 2008 and (ii) the date on which Quest commercializes the three diagnostic tests. On October 24, 2008, Vermillion and Quest amended the Strategic Alliance Agreement to extend the term of the agreement to end on the earlier of (i) September 1, 2009 and (ii) the date on which Quest commercializes the three diagnostic tests. Subsequently on October 7, 2009, Vermillion and Quest amended the Strategic Alliance Agreement to extend the term of the agreement to end on the earlier of (i) October 7, 2012 and (ii) the date on which Quest makes its third development election. To date, Quest has selected only two diagnostic tests, which are VASCLIR and the OVA1 Test, to commercialize. Currently all of our revenue comes from Quest pursuant to the Strategic Alliance. If the Strategic Alliance were to terminate, it could significantly impact our ability to generate revenue.

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

We believe that our current cash resources together with existing debt facilities will be sufficient to meet our anticipated needs for the next 12 months. However, we may need to raise additional capital sooner in order to develop new or enhanced products or services, increase our efforts to discover biomarkers and develop them into diagnostic products, or acquire complementary products, businesses or technologies. We may seek to raise additional capital through the issuance of equity or debt securities, or a combination thereof, 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 or convertible senior notes. If we raise additional funds by issuing debt, we may be subject to limitations on its 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.

Substantial leverage and debt service obligations may adversely affect our consolidated cash flows.

As of September 30, 2010, we had \$5,000,000 of outstanding principal of our 7.00% Notes and \$7,000,000 outstanding under our secured line of credit with Quest.

Quest provided us with \$10,000,000 secured line of credit, which was forgivable based upon the achievement of certain milestones related to the development, regulatory approval and commercialization of certain diagnostic tests. As of our emergence from bankruptcy, certain milestones had been met and the principal balance of the secured line of credit was reduced to \$7,000,000. The \$7,000,000 secured line of credit is secured by our assets, and is senior to the outstanding \$5,000,000 of the 7.00% Notes. As a result of this indebtedness, we have substantial principal and interest payment obligations. The degree to which we are leveraged could, among other things:

make it difficult for us to obtain financing for working capital, acquisitions or other purposes on favorable terms, if at all;

make us more vulnerable to industry downturns and competitive pressures; and

limit our flexibility in planning for or reacting to changes in our business.

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control. If we cannot meet its debt service obligation, it would have a material adverse effect on our consolidated financial position.

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 sensitivity and specificity. If we do succeed in developing additional diagnostic tests with acceptable performance characteristics, we may not succeed in achieving significant commercial market acceptance for those tests. Our ability to successfully commercialize diagnostic products, such as tests, kits and devices, will depend on several factors, including:

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

our ability to further establish business relationships with other diagnostic or laboratory companies that can assist in the commercialization of these products; and

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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 our products.

These factors present obstacles to significant commercial acceptance of our potential diagnostic products, 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 space 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 current clinical practices (e.g. those of obstetricians and gynecologists and gynecologic oncologists in the case of the OVA1 Test). We believe that the OVA1 Test provides a significant improvement over current clinical practices, but if we are not able to convince clinicians of this, our ability to commercialize the OVA1 Test would be adversely affected. The field of ovarian cancer diagnostics generally, and the management of ovarian adnexal masses, specifically, are competitive. Certain companies have publicly disclosed that they have been or are currently working on ovarian cancer diagnostic assays. Additionally, academic institutions periodically report new findings in ovarian cancer diagnostics that may have commercial value. Our failure to compete with any competitive diagnostic assays if and when commercialized could adversely affect our business.

We have priced the OVA1 Test 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 the OVA1 Test in efficacy but is priced at a lower point, we may have to lower the price of the OVA1 Test, 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 the OVA1 Test on September 11, 2009. 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 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 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 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.

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We have \$7,000,000 outstanding from the secured line of credit provided by Quest. If we fail to achieve the milestones for the forgiveness of the secured line of credit set forth in our amended credit agreement with Quest, we will be responsible for full repayment of the secured line of credit on or before October 7, 2012.

As of September 30, 2010, we have \$7,000,000 outstanding from the secured lined of credit in connection with the Strategic Alliance. Over a two-year period, we borrowed monthly increments of \$417,000, totaling \$10,000,000, and have paid all interest that was due. Funds from this secured line of credit were used for certain costs and expenses directly related to the Strategic Alliance, with forgiveness of the repayment obligations based upon our achievement of milestones related to the development, regulatory approval and commercialization of certain diagnostic tests. On October 7, 2009, the Strategic Alliance Agreement was amended to extend the term of the agreement to end on the earlier of (i) October 7, 2012 and (ii) the date on which Quest makes its third development election. On September 11, 2009, we announced our milestone achievement of clearing the OVA1 Test with the FDA and, effective after the emergence from Chapter 11 bankruptcy, reduced our principal obligations under the Amended Strategic Alliance Agreement to \$7,000,000. Should we fail to achieve the remaining milestones, we would be responsible for the repayment of the outstanding principal amount and any unpaid interest on the secured line of credit on or before October 7, 2012, which could materially adversely affect our consolidated 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. In addition to our licensed SELDI technology, we have also submitted patent applications covering biomarkers that may have diagnostic or therapeutic utility. Our patent applications 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 its 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.

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On July 9, 2007, Molecular Analytical Systems filed a lawsuit in the Superior Court of California for the County of Santa Clara naming Vermillion and Bio-Rad as defendants. Under the State Court lawsuit, MAS seeks an unspecified amount of damages and alleges, among other things, that we are in breach of our license agreement with MAS relating to SELDI technology as a result of our entry into a sublicense agreement with Bio-Rad. We filed a petition to compel arbitration, which was denied in the trial court. We then filed our general denial and affirmative defense on April 1, 2008. The Company and Bio-Rad thereafter appealed the denial of the motion to compel arbitration, which appeal had the effect of staying the State Court lawsuit, which stay was further extended in both the state trial and appellate courts when the Company filed on March 30, 2009, a Voluntary Petition for Relief under Chapter 11 in the Bankruptcy Court. MAS filed a proof of claim on June 30, 2009, in connection with our Chapter 11 bankruptcy proceedings. The proof of claim mirrored the MAS lawsuit and asserted that we breached the Exclusive License Agreement by transferring certain technologies to Bio-Rad without obtaining MAS's consent. MAS listed the value of its claim as in excess of \$5,000,000. On December 28, 2009, we objected to MAS's Proof of Claim in the Bankruptcy Court. On January 7, 2010, the Bankruptcy Court confirmed the Company's Plan of Reorganization. Per the Court's order confirming the Plan, the Company's bankruptcy case will be closed when, along with other requirements, a final, non-appealable judgment is entered on MAS's claims. After the Plan of Reorganization was confirmed, MAS filed a motion with the Bankruptcy Court asking it to abstain from hearing its proof of claim and asked the Bankruptcy Court to grant relief from stay so that MAS could proceed with the State Court lawsuit in California. The Bankruptcy Court granted that motion on March 15, 2010. Thereafter, the California Court of Appeal has set oral argument on our appeal of the trial court order denying our motion to compel arbitration for June 17, 2010. The California Court of Appeals overturned the Superior Court's decision in an opinion dated July 9, 2010, and ordered that the dispute be arbitrated before the Judicial Arbitration and Mediation Service (JAMS). MAS filed its demand for arbitration on September 15, 2010. The demand did not include any additional detail regarding MAS's claims, and instead submitted the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. JAMS has not yet set a schedule for resolution of MAS's claims, and management cannot predict the ultimate outcome of this matter at this time.

Our failure to meet its purchase commitments, pursuant to a manufacture and supply agreement with Bio-Rad, could adversely affect our consolidated results of operations and financial condition.

We were a party to a manufacture and supply agreement with Bio-Rad, dated November 13, 2006, whereby we agreed to purchase from Bio-Rad the ProteinChip Systems and ProteinChip Arrays necessary to support our diagnostics efforts. Under the terms of the agreement, we were required to purchase a specified number of ProteinChip Systems and ProteinChip Arrays in each of the three years following the date of the agreement. Pursuant to a letter from us to Bio-Rad dated May 2, 2008, we exercised our right to terminate the agreement for convenience upon 180 days' written notice. Consequently, termination of the agreement became effective on October 29, 2008. As part of the Chapter 11 bankruptcy process, Bio-Rad made a claim for approximately \$1,000,000. If we are unable to renegotiate this claim, it would have an adverse effect on our consolidated cash flows.

If we or our suppliers fail to comply with FDA requirements, we may not be able to market our products and services and may be subject to stringent penalties; further improvements to our or our suppliers' manufacturing operations may be required that would 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 (ASRs) that we may provide will 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 the OVA1 Test 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 the OVA1 Test. 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 diagnostics efforts.

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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 bioinformatics, biochemistry and information services. Competition for qualified employees is intense.

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

The testing, manufacturing and marketing of medical diagnostic tests entails 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 against which it is not indemnified 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.

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 enacted 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. We have completed the process of documenting our systems of internal control and have evaluated our systems of internal control. Beginning with the year ended December 31, 2004, we have been required to assess continuously our compliance with Section 404 of the Sarbanes-Oxley Act of 2002. We expect to continue to devote the necessary resources, including internal and external resources, to support our assessment. In the future, if we identify one or more material weaknesses, or our independent registered public accounting firm is unable to attest that our report is fairly stated or to express an opinion on the effectiveness of our internal controls over financial reporting, this could result in a loss of investor confidence in our financial reports, have an adverse effect on our stock price and/or subject us to sanctions or investigation by regulatory authorities. Compliance with these evolving standards will result in increased general and administrative expenses and may cause a diversion of our time and attention from revenue-generating activities to compliance activities.

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

In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"), 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%.

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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

Our common stock was re-listed on The NASDAQ Global Market on July 6, 2010. The liquidity and trading volume of our common stock may continue to be low.

On July 6, 2010, our common stock was re-listed on The NASDAQ Global Market. However, the liquidity and trading volume of our common stock may continue to be low. If the liquidity and trading volume were to fall further, this could impact the trading price of our shares and adversely affect its ability to issue stock.

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:

our emergence from bankruptcy under Chapter 11, and the risks, uncertainties and difficulties related thereto;

failure to significantly increase revenue;

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;

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comments or opinions by securities analysts or major stockholders;

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

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

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

litigation or threat of litigation;

additions or departures of key personnel;

limited daily trading volume;

economic and other external factors, disasters or crises.

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In addition, the stock market in general and the market for 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. Further, there has been significant volatility in the market prices of securities of life science 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.

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

Our certificate of incorporation, bylaws and stockholder rights plan contain provisions that could make it more difficult for a third party to acquire the Company, even if doing so might be deemed beneficial by our stockholders. 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. The rights issued pursuant to our stockholder rights plan will become exercisable the tenth day after a person or group announces acquisition of 15% or more of our common stock or announces commencement of a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of our common stock. If the rights become exercisable, the holders of the rights (other than the person acquiring 15% or more of our common stock) will be entitled to acquire, in exchange for the rights' exercise price, shares of our common stock or shares of any company in which the Company is merged, with a value equal to twice the rights' exercise price.

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. In such circumstances, or upon conversion of our senior convertible notes, exercises of currently outstanding options and warrants, and vesting of restricted stock, the ownership interests of our stockholders prior to such sale, conversion or exercise could be substantially diluted. The possibility of dilution posed by shares available for future sale could reduce the market price of our common stock and could make it more difficult for us to raise funds through equity offerings in the future.

As of September 30, 2010, we had 10,416,085 shares of our common stock outstanding and 1,102,683 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 841,485 shares of our common stock that were subject to outstanding options. We granted 302,541 shares of restricted stock to the Directors pursuant to the Debtor's Incentive Plan and 25,000 shares of restricted stock awards to certain employees pursuant to the 2010 Plan. These shares are subject to a vesting schedule of twenty-four months beginning June 22, 2009. In addition, as of September 30, 2010, warrants to purchase 415,782 shares of our common stock were outstanding at exercise prices ranging from \$9.25 to \$25.00 per share, with a weighted average exercise price of \$17.59 per share. Also at September 30, 2010, there were 250,000 shares of our common stock reserved for issuance upon conversion of the 7.00% Notes.

The exercise or conversion of all or a portion of our senior notes, outstanding options and warrants, and the vesting of the restricted stock would 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.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On September 3, 2010, we distributed 70,590 shares of our common stock to our Directors pursuant to the Incentive Plan approved by the Bankruptcy Court. The shares were issued to the Directors as incentive payments for their services rendered to help achieve a successful restructuring of the Company, and therefore no consideration was paid by the Directors to the Company in exchange of the shares. The shares issued are exempted from the registration requirement pursuant to Section 1145(a)(1) of the Bankruptcy Code.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. REMOVED AND RESERVED

None.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

(a) The following exhibits are filed with this report as indicated below:

- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.0 Certification of the Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

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

Vermillion, Inc.

Date: November 12, 2010

/s/ GAIL S. PAGE
Gail S. Page

Executive Chairperson and Chief Executive Officer

(Principal Executive Officer)

Date: November 12, 2010

/s/ SANDRA A. GARDINER
Sandra A. Gardiner

Vice President and Chief Financial Officer

(Principal Financial Officer)