VERMILLION, INC.
Form 10-Q
August 09, 2011
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

(Mark One)

x **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
**For the quarterly period ended June 30, 2011.**

**OR**

¨ **Transition Report under Section 13 or 15(d) of the Securities Exchange Act of 1934.**
**For the transition period from to .**

**Commission File Number: 001-34810**

# Vermillion, Inc.

**(Exact name of registrant as specified in its charter)**

| | |
|---|---|
| **Delaware** | **33-0595156** |
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **12117 Bee Caves Road, Building Three, Suite 100, Austin, Texas** | **78738** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**(512) 519-0400**

**(Registrant s telephone number, including area code)**

**Not applicable**

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

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ¨ | Accelerated filer | ¨ |
| Non-accelerated filer | ¨ (Do not check if a smaller reporting company) | Smaller reporting company | x |

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

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

As of July 31, 2011, the Registrant had 14,811,601 shares of common stock, par value $0.001 per share, outstanding.

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**VERMILLION, INC.**

**FORM 10-Q**

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

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PART I - FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

Vermillion, Inc.

Consolidated Balance Sheets

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

(Unaudited)

| | June 30, 2011 | December 31, 2010 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 36,285 | $ 22,914 |
| Accounts receivable | 115 | 136 |
| Prepaid expenses and other current assets | 420 | 779 |
| Total current assets | 36,820 | 23,829 |
| Property and equipment, net | 253 | 194 |
| Other assets | 12 | 12 |
| Total assets | $ 37,085 | $ 24,035 |
| **Liabilities and Stockholders Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,670 | $ 998 |
| Accrued liabilities | 3,380 | 3,056 |
| Convertible senior notes | 5,000 | 5,000 |
| Deferred revenue | 1,001 | 1,049 |
| Total current liabilities | 11,051 | 10,103 |
| Long-term debt owed to related party | 7,000 | 7,000 |
| Warrant liability | 36 | 378 |
| Deferred revenue | 1,451 | 1,679 |
| Other liabilities | 156 | 259 |
| Total liabilities | 19,694 | 19,419 |
| Commitments and contingencies (Note 5) | | |
| Stockholders equity: | | |
| Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding at June 30, 2011 and December 31, 2010, respectively | | |
| Common stock, $0.001 par value, 150,000,000 shares authorized at June 30, 2011 and December 31, 2010; 14,811,601 and 10,657,564 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively | 15 | 11 |
| Additional paid-in capital | 326,044 | 303,270 |
| Accumulated deficit | (308,513) | (298,509) |
| Accumulated other comprehensive loss | (155) | (156) |

| | | |
|---|---|---|
| Total stockholders equity | 17,391 | 4,616 |
| Total liabilities and stockholders equity | $ 37,085 | $ 24,035 |

See accompanying notes to the consolidated financial statements.

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**Vermillion, Inc.**

**Consolidated Statement of Operations**

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

(Unaudited)

| | Three Months Ended June 30, 2011 | Three Months Ended June 30, 2010 | Six Months Ended June 30, 2011 | Six Months Ended June 30, 2010 |
|---|---|---|---|---|
| Revenue: | | | | |
| Product revenue | $ 191 | $ 45 | $ 508 | $ 45 |
| License revenue | 113 | 299 | 227 | 372 |
| Total revenue | 304 | 344 | 735 | 417 |
| Cost of revenue: | | | | |
| Product | 37 | 12 | 79 | 12 |
| Total cost of revenue | 37 | 12 | 79 | 12 |
| Gross profit | 267 | 332 | 656 | 405 |
| Operating expenses: | | | | |
| Research and development[1] | 1,631 | 938 | 2,849 | 1,686 |
| Sales and marketing[2] | 1,503 | 533 | 2,821 | 726 |
| General and administrative[3] | 2,730 | 2,604 | 5,030 | 4,740 |
| Total operating expenses | 5,864 | 4,075 | 10,700 | 7,152 |
| Loss from operations | (5,597) | (3,743) | (10,044) | (6,747) |
| Interest income | 21 | 7 | 37 | 13 |
| Interest expense | (115) | (115) | (230) | (258) |
| Change in fair value and gain from exercise of warrants, net | 35 | 3,453 | 342 | 3,447 |
| Debt conversion costs | | | | (141) |
| Reorganization items | (16) | (265) | (32) | (1,597) |
| Reorganization items - related party incentive plan | | | | (6,932) |
| Other income (expense), net | (41) | (35) | (77) | (69) |
| Loss before income taxes | (5,713) | (698) | (10,004) | (12,284) |
| Income tax expense | | | | |
| Net loss | $ (5,713) | $ (698) | $ (10,004) | $ (12,284) |
| Net loss per share - basic and diluted | $ (0.39) | $ (0.07) | $ (0.73) | $ (1.20) |
| Weighted average common shares used to compute basic and diluted net loss per common share | 14,736,939 | 10,303,199 | 13,645,520 | 10,217,928 |
| Non-cash stock-based compensation expense included in operating expenses: | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| (1) Research and development | $ | 203 | $ | 199 | $ | 409 | $ | 505 |
| (2) Sales and marketing | | 39 | | 18 | | 82 | | 25 |
| (3) General and administrative | | 1,050 | | 982 | | 2,053 | | 1,618 |

See accompanying notes to the consolidated financial statements.

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**Vermillion, Inc.**

**Consolidated Statements of Cash Flows**

(Amounts in Thousands)

(Unaudited)

| | Six Months Ended June 30, 2011 | 2010 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| Net loss | $ (10,004) | $ (12,284) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Change in warrant value and gain from warrant exercise, net | (342) | (3,447) |
| Accrued incentive plan with related parties | | 3,313 |
| Non-cash license revenue | (227) | (372) |
| Depreciation and amortization | 34 | 88 |
| Debt conversion costs | | 141 |
| Loss on sale and disposal of property and equipment | | 61 |
| Stock-based compensation expense | 2,544 | 767 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 21 | (164) |
| Prepaid expenses and other assets | 359 | (102) |
| Accounts payable, accrued liabilities and other liabilities | 1,231 | 433 |
| Deferred revenue | (49) | 119 |
| Reorganization Items | (338) | (3,353) |
| Net cash used in operating activities | (6,771) | (14,800) |
| **Cash flows from investing activities:** | | |
| Purchase of property and equipment | (93) | (94) |
| Proceeds from sale of property and equipment | | 4 |
| Net cash used in investing activities | (93) | (90) |
| **Cash flows from 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 sale of common stock, net of issuance costs | 20,206 | 42,782 |
| Proceeds from issuance of common stock from exercise of stock options | 28 | 22 |
| Issuance costs related to stock warrant exercises | | (133) |
| Issuance costs related to conversion of convertible senior notes | | (46) |
| Net cash provided by financing activities | 20,234 | 40,030 |
| Effect of exchange rate changes on cash and cash equivalents | 1 | 3 |
| Net increase in cash and cash equivalents | 13,371 | 25,143 |
| Cash and cash equivalents, beginning of period | 22,914 | 3,440 |
| Cash and cash equivalents, end of period | $ 36,285 | $ 28,583 |

| | | | | |
|---|---|---|---|---|
| **Supplemental disclosure of cash flow information:** | | | | |
| Cash paid during the period for: | | | | |
| Interest | $ | 231 | $ | 1,175 |
| Noncash investing and financing activities: | | | | |
| Principal reduction from conversion of senior convertible notes | $ | | $ | (170) |
| Principal reduction from forgiveness of Quest Diagnostics secured line of credit | | | | (3,000) |
| Issuance of common stock from warrant exercise | | | | 1,059 |
| Issuance of common stock from conversion of principal and interest for senior convertible notes | | | | 504 |
| Unrealized loss (gain) on investments | | | | 61 |

See accompanying notes to the consolidated financial statements.

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**Vermillion, Inc.**

**Notes to Consolidated Financial Statements**

(Unaudited)

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

***Organization***

Vermillion, Inc. ( Vermillion ; Vermillion and its wholly-owned subsidiaries are collectively referred to as we or the Company ) is incorporated in the state of Delaware and is engaged in the business of developing and commercializing diagnostics tests in the fields of oncology, cardiology and women s health. On March 9, 2010, we commercially launched the OVA1® ovarian tumor triage test ( OVA1 ) and on September 20, 2010, OVA1 was CE marked, a requirement for marketing the test in the European Union. On April 2, 2011, the Company entered into Amendment No. 5 to the Strategic Alliance Agreement ( Amendment No. 5 ) with Quest Diagnostics Incorporated ( Quest Diagnostics ) and Quest Diagnostic India Private Limited ( Quest Diagnostics India ). Pursuant to Amendment No. 5, Quest Diagnostics India will have the exclusive right to commercialize OVA1 in India for a certain period of time, as specified in the Strategic Alliance Agreement, as amended.

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 OVA1. 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, 2010, 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, 2010, included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC ) on February 25, 2011.

The Financial Accounting Standards Board s ( FASB ) Accounting Standards Codification ( ASC or Codification ) 852 Reorganizations applied 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.

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.

***Significant Accounting and Reporting Policies***

We have made no significant changes in our critical accounting policies and significant estimates from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the SEC on February 25, 2011.

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## 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.

***Reorganization Items***

Professional advisory fees and other costs directly associated with our 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 six months ended June 30, 2011 and 2010 consisted of the following items:

| (in thousands) | Three Months Ended June 30, 2011 | Three Months Ended June 30, 2010 | Six Months Ended June 30, 2011 | Six Months Ended June 30, 2010 |
|---|---|---|---|---|
| Debtors reorganization items | | | | |
| Professional fees associated with bankruptcy proceedings | $ 15 | $ 161 | $ 31 | $ 857 |
| Related party incentive plan | | | | 6,932 |
| Total debtors reorganization items | 15 | 161 | 31 | 7,789 |
| Non-Debtors reorganization items | | | | |
| Professional fees associated with bankruptcy proceedings | 1 | 104 | 1 | 740 |
| Total reorganization items | $ 16 | $ 265 | $ 32 | $ 8,529 |

***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 Diagnostics Credit Agreement and the Patent Security Agreement (the secured line of credit ) was reinstated and unimpaired. Holders of the outstanding 4.50% Convertible Senior Notes (the 4.50% Notes ) received the payment of $2,195,000 of principal, the unpaid interest of $140,000 and 9,044 shares of common stock in exchange for their claims. $5,000,000 in principal of the outstanding 7.00% Convertible Senior Notes (the 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 5);

Bio-Rad Laboratories, Inc. Matters (see Note 5);

$1,000,000 milestone under the Strategic Alliance Agreement with Quest Diagnostics (see Note 4); and

various pre-petition liability objections.

### 3. Recent Accounting Pronouncements

Fair Value Measurement In April 2011, the FASB issued new guidance to achieve common fair value measurement and disclosure requirements between GAAP and International Financial Reporting Standards. This new guidance amends current fair value measurement and disclosure guidance to include increased transparency around valuation inputs and investment categorization. The new guidance is effective for fiscal years and interim periods beginning after December 15, 2011. We do not believe the adoption of the new guidance will have an impact on our consolidated financial position, results of operations or cash flows.

Comprehensive Income In June 2011, the FASB issued new guidance on the presentation of comprehensive income. Specifically, the new guidance allows an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. While the new guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. We will adopt this pronouncement in the first quarter of 2012, and it will have no effect on our financial position or results of operations but it will impact the way we present comprehensive income.

### 4. Secured Line of Credit with Quest Diagnostics Incorporated

On July 22, 2005, in connection with our Strategic Alliance Agreement with Quest Diagnostics, Quest Diagnostics provided us with a $10,000,000 secured line of credit, which was collateralized by certain of our intellectual property, used only for payment of certain costs and expenses directly related to developing and commercializing 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 prime rate plus 0.5%, payable monthly. If, in the event of 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 Diagnostics to forgive portions of the amounts borrowed that correspond to our achievement of certain milestones related to development, regulatory approval and commercialization of certain diagnostic tests. The amounts to be forgiven and the corresponding milestones we must achieve are:

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

(ii) $3,000,000 for the earlier of the United States Food and Drug Administration (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 OVA1 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. The outstanding principal balance of this secured line of credit was $7,000,000 at June 30, 2011 and December 31, 2010. We are in discussions with Quest Diagnostics regarding the achievement of an additional $1,000,000 forgiveness milestone related to OVA1 under the terms of the Strategic Alliance Agreement.

### 5. 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 ended 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 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 $54,000 and $109,000 for the three and six months ended June 30, 2011, and $48,000 and $207,000 for the three and six months ended June 30, 2010, 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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In June 2010, we entered into non-cancelable 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, we relocated our corporate headquarters from Fremont, California to Austin, Texas. 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 as defendants (the State Court lawsuit ). Under the State Court lawsuit, MAS sought an unspecified amount of damages and alleged, among other things, that we are in breach of a license agreement with MAS relating to the Surface Enhanced Laser Desorption/Ionization ( 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 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 we filed a Voluntary Petition for Relief under Chapter 11 in the Bankruptcy Court on March 30, 2009. MAS filed a proof of claim on July 15, 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 our Plan of Reorganization. Per the Court s order confirming the Plan, our 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 the automatic stay so that MAS could proceed with the State Court lawsuit in California. Over our objection, the Bankruptcy Court granted that motion on March 15, 2010. Thereafter, the California Court of Appeal 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 submitted the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. The parties are currently conducting discovery and the Arbitrator has set September 21, 2011 as the date on which a hearing will commence on MAS s claims. An unfavorable judgment against us could require us to pay monetary damages. Management does not believe an unfavorable outcome is probable, or even reasonably possible for which an amount or range of loss can be estimated such that would require an accrual or disclosure under ASC 450, contingencies; however, management cannot predict the ultimate outcome of this matter at this time.

*Bio-Rad Laboratories, Inc. Matters*

On November 13, 2006, we completed the Instrument Business Sale to Bio-Rad. The Instrument Business Sale included the 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 us 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 our meeting certain obligations, of which $2,000,000 was subsequently paid to us 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 us to fulfill certain obligations.

In connection with the Instrument Business Sale, we entered into a letter agreement with Bio-Rad pursuant to which we 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 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 MAS claim and cannot predict the ultimate outcome of this matter at this time.

In connection with the Instrument Business Sale, we 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 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 us 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 at June 30, 2011 and December 31, 2010. 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.

## 6. Comprehensive Loss

The components of accumulated other comprehensive loss as of June 30, 2011 and December 31, 2010 were as follows:

| (in thousands) | June 30, 2011 | December 31, 2010 |
|---|---|---|
| Cumulative translation adjustment | $ (155) | $ (156) |
| | $ (155) | $ (156) |

Comprehensive loss for the three and six months ended June 30, 2011 and 2010 was as follows:

| (in thousands) | Three months ended June 30, 2011 | Three months ended June 30, 2010 | Six months ended June 30, 2011 | Six months ended June 30, 2010 |
|---|---|---|---|---|
| Net loss | $ (5,713) | $ (698) | $ (10,004) | $ (12,284) |
| Net unrealized gain on long-term investments | | $ (61) | | (61) |
| Foreign currency translation adjustment | 1 | 4 | | 3 |
| Comprehensive loss | $ (5,712) | $ (755) | $ (10,004) | $ (12,342) |

## 7. 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 ). On December 3, 2010, the 2010 Plan was approved by our stockholders. The 2010 Plan is administered by the Compensation Committee of the Board. The Company s employees, directors, and consultants are eligible to receive awards under the 2010 Plan. The 2010 Plan permits the granting of a variety of awards, including stock options, share appreciation rights, restricted shares, restricted share units, unrestricted shares, deferred share units, performance and cash-settled awards, and dividend equivalent rights. The 2010 Plan provides for issuance of up to 1,322,983 shares of common stock, par value $0.001 per share under the 2010 Plan, subject to adjustment as provided in the 2010 Plan.

***Stock-Based Compensation***

*Employee Stock-based Compensation Expense*

During the three and six months ended June 30, 2011, we granted none and 177,000 restricted share units to our executive officers, respectively. The restricted stock has a fair value of $724,000 and vests on a quarterly basis over a three-year period beginning in March 2011. There was no restricted stock granted to our executive officers during the three and six months ended June 30, 2010. We distributed 14,750 shares of common stock to our executive officers during the three months ended June 30, 2011 per the terms of the restricted share unit grant.

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During the three and six months ended June 30, 2011, we granted none and 87,800 restricted share units to our Board of Directors as compensation for their services during 2011. This restricted stock has a fair value of $347,000 and vests 50% on June 1, 2011 and 25% each on September 1, 2011 and December 1, 2011. There was no restricted stock granted to our Board of Directors during the three and six months ended June 30, 2010. We distributed 43,900 shares of common stock to our Board of Directors during the three months ended June 30, 2011 per the terms of the restricted share unit grant.

We granted stock options to purchase up to 6,000 and 36,430 shares of common stock with an average exercise price of $5.16 and $4.30 during the three and six months ended June 30, 2011, respectively. We granted stock options to purchase up to 40,000 and 146,000 shares of common stock with an average exercise price of $19.95 and $26.27 during the three and six months ended June 30, 2010, respectively. 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Dividend yield | 0% | 0% | 0% | 0% |
| Volatility | 79% | 81% | 79% | 82% |
| Risk-free interest rate | 1.83% | 2.25% | 2.01% | 2.57% |
| Expected lives (years) | 5.7 | 5.7 | 5.7 | 5.6 |
| Weighted average fair value | $ 3.45 | $ 13.73 | $ 2.90 | $ 18.20 |

The allocation of employee stock-based compensation expense by functional area for the three and six months ended June 30, 2011 and 2010, respectively, was as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| (in thousands) | 2011 | 2010 | 2011 | 2010 |
| Research and development | $ 203 | $ 199 | $ 409 | $ 467 |
| Sales and marketing | 39 | 18 | 82 | 20 |
| General and administrative | 1,050 | 908 | 2,053 | 1,518 |
| Total | $ 1,292 | $ 1,125 | $ 2,544 | $ 2,005 |

*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 such options remaining outstanding at June 30, 2011. The fair value of the stock options granted were revalued using the Black-Scholes valuation model as prescribed by ASC 505, Equity, using the following average assumptions:

| | Three Months Ended June 30, 2010 | Six Months Ended June 30, 2010 |
|---|---|---|
| Dividend yield | 0% | 0% |
| Volatility | 82% | 82% |
| Risk-free interest rate | 3.13% | 3.19% |
| Expected lives (years) | 7.81 | 7.81 |
| Weighted average fair value | $ 10.79 | $ 14.44 |

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The stock-based compensation expense will fluctuate as the fair market value of the common stock fluctuates. There was no stock-based compensation expense for non-employees during the three and six months ended June 30, 2011. In connection with stock options relating to non-employees, we recorded non-employee stock-based compensation allocated by functional area for the three and six months ended June 30, 2010 as follows:

| (in thousands) | Three Months Ended June 30, 2010 | Six Months Ended June 30, 2010 |
|---|---|---|
| Research and development | $ | $ 38 |
| Sales and marketing | | 5 |
| General and administrative | 74 | 100 |
| Total | $ 74 | $ 143 |

8. **Common Stock**

***February 2011 Follow-on Public Offering***

On February 18, 2011, we completed a sale of 4,000,000 shares of our common stock in an underwritten follow-on public offering at a price of $5.45 per share for $21,800,000 in gross proceeds. Net proceeds of the offering were approximately $20,200,000 after deducting underwriting discounts and expected offering expenses. Roth Capital Partners acted as the sole manager of the offering.

***Common Stock Warrants***

At June 30, 2011 and December 31, 2010, the Company had warrants outstanding to purchase 195,012 shares of common stock that are subject to fair value measurement on a recurring basis. These warrants expire in August 2012. The fair value of these common stock warrants for the three and six months ended June 30, 2011 and 2010 was determined using a Black-Scholes valuation model with the following Level 3 inputs:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Dividend yield | 0% | 0% | 0% | 0% |
| Volatility | 60% | 84% | 59% | 84% |
| Risk-free interest rate | 0.23% | 0.70% | 0.37% | 1.00% |
| Expected lives (years) | 1.17 | 2.17 | 1.30 | 2.30 |
| Weighted average fair value | $ 0.19 | $ 6.59 | $ 0.28 | $ 14.13 |

For the three and six months ended June 30, 2011, income relating to changes in fair value of the common stock warrant liabilities totaled $35,000 and $342,000, respectively. For the three and six months ended June 30, 2010, income relating to changes in fair value of the common stock warrant liabilities totaled $3,352,000 and $3,224,000, respectively. No warrants were exercised during the three months and six months ended June 30, 2011. As a result of warrant exercises, we recognized total gains of $101,000 and $223,000 for the three and six months ended June 30, 2010, respectively. The following table is a reconciliation of the warrant liability measured at fair value using Level 3 inputs for the three and six months ended June 30, 2011 and 2010:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| **(in thousands)** | **2011** | **2010** | **2011** | **2010** |
| Balance at beginning of period | $ 71 | $ 4,884 | $ 378 | $ 5,659 |
| Change in fair value of common stock warrants | (35) | | (342) | |
| Issuance of common stock from warrant exercise | | (3,352) | | (3,224) |
| | | (248) | | (1,151) |

| | | | | |
|---|---|---|---|---|
| Reclassification of warrant fair value to equity upon exercise and issuance of common stock | | | | |
| Balance at end of period | $ 36 | $ 1,284 | $ 36 | $ 1,284 |

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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 June 30, 2011:

| | | Fair Value Measurements at Reporting Date | | |
|---|---|---|---|---|
| (in thousands) | Total Fair Value | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Liabilities:** | | | | |
| Common stock warrants | $ 36 | $ | $ | $ 36 |

**9. 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 1,710,741 and 1,475,573 potential common shares as of June 30, 2011 and 2010, respectively, that are antidilutive. Potential common shares include common shares issuable upon conversion of all convertible senior notes, incremental shares of common stock issuable upon the exercise of outstanding stock options, common stock warrants and restricted stock awards.

**10. Related Party Transactions**

***Consulting Agreements***

On June 17, 2011, we entered into a consulting agreement with Bruce A. Huebner, a member of our Board of Directors. Pursuant to the terms of the consulting agreement, Mr. Huebner is retained as an independent contractor to perform certain consulting services relating to sales, marketing, business development and corporate strategy for us. For the three months ended June 30, 2011, we incurred $2,000 in general and administrative expenses under the consultant arrangement.

On March 26, 2009, we entered into a consulting agreement with our former Chief Executive Officer and current Director. For the three and six months ended June 30, 2010, we incurred none and $24,000 in general and administrative expenses under the consultant 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 and six months ended June 30, 2010, we incurred none and $14,272 in research and development expenses under the consulting arrangement. On February 1, 2010, this consulting agreement was terminated when we re-hired our Senior Vice President and Chief Science Officer.

***Quest Diagnostics***

Quest Diagnostics is a significant stockholder and the holder of our Secured Line of Credit (see Note 5). Accounts receivable from Quest Diagnostics under the Strategic Alliance Agreement totaled $99,000 and $121,000 at June 30, 2011 and December 31, 2010, respectively.

***Debtor s Incentive Plan***

In connection with the Bankruptcy Filing, on April 21, 2009, the Company filed the Debtor s Motion for Entry of an Order Approving the Debtor s 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 was to be distributed, with 1/24th of it vesting 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 $1,656,000 for the three and six months ended June 30, 2011, respectively. The Company recorded a charge of $828,000 and $8,313,000 for the three and six months ended June 30, 2010, respectively. The expense for the three and six months ended June 30, 2011 was recorded in general and administrative expenses. As of June 30, 2010, the Company incurred $8,313,000 under the terms of the Incentive Plan, of which $6,932,000 was recorded in Reorganization Items for the period prior to emerging out of bankruptcy and $1,381,000 was recorded in general and administrative expenses for the period subsequent to emerging out of bankruptcy. In April 2010, the Company distributed an aggregate of $5,000,000 in cash to the Directors. As of June 30, 2011, all 302,541 shares of common stock were distributed to the Directors under the Incentive Plan.

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**11. Subsequent Events**

On August 1, 2011, we entered into an Exclusive Distribution Agreement (the Pronto Agreement ) with Pronto Diagnostics Ltd. ( Pronto Diagnostics ). Pursuant to the Pronto Agreement, Pronto Diagnostics will have the exclusive right to distribute OVA1 in Israel and areas under Palestinian control for a certain period of time as specified in the Pronto Agreement, provided that Pronto Diagnostics will sell certain minimum quantities of OVA1 to maintain the exclusive distribution rights. The Pronto Agreement also establishes the amounts that Pronto Diagnostics will pay to us with respect of OVA1. A copy of the Pronto Agreement is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q.

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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 the negative of such terms or ot 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 Diagnostics;
- our ability to comply with applicable government regulations;
- our ability to expand and protect our intellectual property portfolio;
- anticipated future losses;
- expected levels of expenditures;
- expected market adoption of our diagnostic tests, including OVA1;
- our ability to obtain reimbursement for our diagnostic tests, including OVA1;

- forgiveness of the outstanding principal amounts of the secured line of credit by Quest Diagnostics;
- accounting treatment of revenue from our agreement with Quest Diagnostics;
- the period of time for which our existing financial resources, debt facilities and interest income will be sufficient to enable us to maintain current and planned operations; 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 OVA1 or future diagnostic products, including the risk that our products will not be competitive with products offered by other companies, or that users will not be entitled to receive adequate reimbursement for our products from third party payers such as private insurance companies and government insurance plans; our ability to successfully license or otherwise successfully partner with third parties to 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.

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*Overview*

We are dedicated to the development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Our tests are intended to help guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, or to assist in 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 have.

Management ( we , us or our ) concentrates its development of novel diagnostic tests in the fields of oncology, 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 and through our strategic alliance agreement with Quest Diagnostics.

On March 30, 2009, we filed for relief under the Chapter 11 of the Bankruptcy Code. We emerged from bankruptcy protection on January 22, 2010, pursuant to the terms of a January 5, 2010 order entered by the Bankruptcy court approving our Second Amended Plan of Reorganization under Chapter 11.

Our lead product, OVA1, was cleared by the FDA on September 11, 2009 and is currently being offered by Quest Diagnostics. OVA1 addresses a clear unmet clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary FDA-cleared software to determine the likelihood of malignancy in women over age 18 with a pelvic mass for whom surgery is planned.

OVA1 was developed through large pre-clinical studies in collaboration with numerous academic medical centers encompassing over 2,500 clinical samples. OVA1 was fully validated in a prospective multi-center clinical trial encompassing 27 sites reflective of the diverse nature of the clinical centers at which ovarian adnexal masses are evaluated. The results of the clinical trial demonstrated that among non-gynecologic oncologists, OVA1, in conjunction with clinical evaluation, was able to identify 91.7% of the malignant ovarian tumors and to rule out malignancy (negative predictive value, NPV) with 93.2% certainty. Data were presented at the 2010 International Gynecologic Cancer Society Meeting demonstrating the high sensitivity of OVA1 for epithelial ovarian cancers; overall OVA1 detected 95/96 epithelial ovarian cancer cases for a sensitivity of 99.0%, including 40/41 stage I and stage II epithelial ovarian cancers, for an overall sensitivity of 97.6% for early stage epithelial ovarian cancers, as compared to 65.9% for CA125 using the American College of Obstetricians and Gynecologists ( ACOG ) cutoffs. The improvement in sensitivity was even greater among premenopausal women; for OVA1, sensitivity for early stage epithelial ovarian cancer was 92.9% and for CA125, sensitivity was 35.7%. Overall, OVA1 detected 76% of malignancies missed by CA125, including all advanced stage malignancies. OVA1 is not indicated for use as a screening or stand-alone diagnostic assay. In June 2011, two peer review articles were published in *Obstetrics & Gynecology*, which is the official publication of the ACOG, showing OVA1 s value in evaluating women with an adnexal mass for the likelihood of ovarian cancer prior to surgery. The papers demonstrated that adding OVA1 to a physician s preoperative assessment of a woman s ovarian mass would identify more ovarian cancers than a physician s preoperative assessment alone.

The Medicare contractor Highmark Medicare Services has been covering OVA1 in its reimbursement program since March 2010. As of the date of this filing, patient coverage for OVA1 has been recently expanded with the addition of Blue Cross Blue Shield ( BCBS ) of Rhode Island and Western New York, Premera BCBS of Washington and Alaska and Blue Shield of Northeastern New York. In all, 22 independent BCBS plans, representing approximately 36.0 million lives, are covering OVA1. Including Medicare and other regional plans, we believe total coverage for OVA1 is now approximately 82.5 million lives.

Under the terms of our Strategic Alliance Agreement with Quest Diagnostics, as amended, Quest Diagnostics is required to pay us a fixed payment of $50 per OVA1 performed, as well as 33% of its gross margin from revenue from performing OVA1 domestically, as that term is defined in the Strategic Alliance Agreement as amended. Quest Diagnostics is the exclusive clinical laboratory provider of OVA1 in its exclusive territory, which includes the US, Mexico, the United Kingdom and India through September 11, 2014. OVA1 was CE marked in September 2010, a requirement for marketing the test in the European Union. OVA1 was launched in India in May 2011. Quest Diagnostics has the right to extend the exclusivity period for an additional year beyond September 11, 2014 on the same terms and conditions.

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On August 1, 2011, we entered into the Pronto Agreement with Pronto Diagnostics. Pursuant to the Pronto Agreement, Pronto Diagnostics will have the exclusive right to distribute OVA1 in Israel and areas under Palestinian control for a certain period of time as specified in the Pronto Agreement, provided that Pronto Diagnostics will sell certain minimum quantities of OVA1 to maintain the exclusive distribution rights. The Pronto Agreement also establishes the amounts that Pronto Diagnostics will pay to us with respect of OVA1. This supports our goal of expanding OVA1 into international markets.

In addition to OVA1, 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 establish and 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 May 17, 2011, we announced that the United States Patent and Trademark Office ( USPTO ) has issued a notice of allowance to us for a patent entitled Panel of Biomarkers for Peripheral Artery Disease . The patent covers biomarker panels for the diagnosis of Peripheral Artery Disease. The data supporting the patent were published in an article titled, A biomarker panel for peripheral arterial disease, in Vasc Med. 2008 Aug; 13(3):217 24. This work was done in coordination with Dr. John Cooke at Stanford University. Dr. Cooke is Professor and Associate Director of the Stanford Cardiovascular Institute at Stanford University School of Medicine.

On May 19, 2011, we announced the appointment of Bruce Huebner to our Board of Directors. Mr. Huebner currently serves as Managing Director at LynxCom Partners, LLC a Healthcare Consulting Firm. Mr. Huebner has over 35 years of experience in the diagnostic industry, and has been a key member of upper management in a number of clinical diagnostic companies including Hybritech, Inc., Gen-Probe, Inc., Nanogen, Inc. and Osmetech Molecular Diagnostics.

On May 25, 2011, we announced that the USPTO has issued a notice of allowance to us for a patent entitled Saposin D and Fam3C are Biomarkers for Alzheimer s Disease. The patent claims cover the biomarkers saposin D and Fam3c as well as combinations that include these biomarkers.

On June 24, 2011, we were added to the Russell Microcap Index. Membership in the Russell Microcap Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes. Russell determines membership for its equity indexes primarily by objective, market-capitalization rankings and style attributes.

On August 1, 2011, we announced that the USPTO has issued a notice of allowance to us for a patent entitled Biomarkers for Peripheral Artery Disease. The patent claims cover the biomarker alpha1beta glycoprotein and biomarker combinations that include alpha1beta glycoprotein for the diagnosis of PAD.

On August 2, 2011, we announced that the USPTO has issued a notice of allowance to us for a patent entitled Beta-2 microglobulin as a Biomarker for Peripheral Artery Disease. The patent covers various potential permutations of candidate biomarkers and will therefore cover a broad range of possibilities in our intended use study.

***Critical Accounting Policies and Significant Estimates***

We have made no significant changes in our critical accounting policies and significant estimates from those disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the SEC on February 25, 2011.

***Recent Accounting Pronouncements***

Fair Value Measurement In April 2011, the FASB issued new guidance to achieve common fair value measurement and disclosure requirements between GAAP and International Financial Reporting Standards. This new guidance amends current fair value measurement and disclosure guidance to include increased transparency around valuation inputs and investment categorization. The new guidance is effective for fiscal years and interim periods beginning after December 15, 2011. We do not believe the adoption of the new guidance will have an impact on our consolidated financial position, results of operations or cash flows.

Comprehensive Income In June 2011, the FASB issued new guidance on the presentation of comprehensive income. Specifically, the new guidance allows an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. While the new guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. We will adopt this pronouncement in the first quarter of 2012, and it will have no effect on our financial position or results of operations but it will impact the way we present comprehensive income.

***Results of Operations - Three Months Ended June 30, 2011 Compared to Three Months Ended June 30, 2010***

The selected summary financial and operating data of Vermillion for the three months ended June 30, 2011 and 2010, were as follows:

| (dollars in thousands) | Three Months Ended June 30, 2011 | 2010 | Increase (Decrease) Amount | % |
|---|---|---|---|---|
| Revenue: | | | | |
| Product | $ 191 | $ 45 | $ 146 | 324 |
| License | 113 | 299 | (186) | (62) |
| Total revenue | 304 | 344 | (40) | (12) |
| Cost of revenue: | | | | |
| Product | 37 | 12 | 25 | 208 |
| Total cost of revenue | 37 | 12 | 25 | 208 |
| Gross profit | 267 | 332 | (65) | (20) |
| Operating expenses: | | | | |
| Research and development | 1,631 | 938 | 693 | 74 |
| Sales and marketing | 1,503 | 533 | 970 | 182 |
| General and administrative | 2,730 | 2,604 | 126 | 5 |
| Total operating expenses | 5,864 | 4,075 | 1,789 | 44 |
| Loss from operations | (5,597) | (3,743) | (1,854) | 50 |
| Interest income | 21 | 7 | 14 | 200 |
| Interest expense | (115) | (115) | | |
| Change in fair value and gain from exercise of warrants, net | 35 | 3,453 | (3,418) | (99) |
| Reorganization items | (16) | (265) | 249 | (94) |
| Other income (expense), net | (41) | (35) | (6) | 17 |
| Loss before income taxes | (5,713) | (698) | (5,015) | 718 |
| Income tax benefit (expense) | | | | |
| Net loss | $ (5,713) | $ (698) | $ (5,015) | 718 |

***Product Revenue***. Product revenue was $191,000 for the three months ended June 30, 2011 compared to $45,000 for the same period in 2010. We recognized product revenue for the three months ended June 30, 2011 for the sale of OVA1 through Quest Diagnostics. Quest Diagnostics performed approximately 3,920 OVA1 tests during the three months ended June 30, 2011 compared to 342 tests for the same period in 2010. We commercially launched OVA1 on March 9, 2010. Product revenue increased $146,000 for the three months ended June 30, 2011 compared to the same period in 2010 due to the increased volume of tests. The timing of revenue recognition for the payments associated with the increased number of tests was impacted by the November 10, 2010 Amendment No. 4 to the Strategic Alliance Agreement with Quest Diagnostics ( Quest Amendment No. 4 ). Product revenue for the three months ended June 30, 2011 was derived solely from domestic sales of OVA1.

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***License Revenue***. License revenue was $113,000 for the three months ended June 30, 2011 compared to $299,000 for the same period in 2010. Under the terms of our secured line of credit with Quest Diagnostics, $3,000,000 principal was forgiven upon the achievement of FDA clearance of OVA1. This amount is recognized as license revenue straight-lined over the period of sales exclusivity Quest Diagnostics received beginning on OVA1 s commercialization date of March 9, 2010. License revenue decreased $186,000, or 62%, for the three months ended June 30, 2011 compared to the same period in 2010 due to the extension of the term of exclusivity for up to three additional years in Quest Amendment No. 4. The balance of the $3,000,000 forgiven will be recognized over the revised period of exclusivity.

***Product Cost of Sales***. Cost of product revenue includes royalties on net sales paid to JHU, as well as sample acquisition and lot qualification costs related to the testing of reagent lots for the assays included in OVA1 to ensure they meet the specifications required for inclusion. Product cost of sales was $37,000 for the three months ended June 30, 2011 compared to $12,000 in the same period in 2010 due to increased sample acquisition and lot qualification costs related to increased OVA1 sales volume requiring more frequent lot qualification.

***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 $693,000, or 74%, for the three months ended June 30, 2011 compared to the same period in 2010. This increase was due primarily to a $778,000 increase in clinical trial and collaboration costs for the ongoing development of our ovarian cancer program and our PAD blood test, VASCLIR , partially offset by decreases in depreciation expense and losses on disposal of property and equipment compared to the same period in 2010.

***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 OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and health economic publications. Our personnel-related expenses include the cost of our Territory Development Managers, the subject matter experts responsible for market development and the coordination of interactions with the Quest Diagnostics sales team. Sales and marketing expenses increased by $970,000, or 182%, for the three months ended June 30, 2011 compared to the same period in 2010. The increase was primarily due to a $656,000 increase in personnel and personnel-related expenses, reflecting 19 sales and marketing related personnel at June 30, 2011 compared to nine sales and marketing related personnel at June 30, 2010. Trade show, advertising and marketing expenses increased $210,000 related to the continuing cost of OVA1 promotion and education. We expect sales and marketing expenses to increase in future periods due to our continued efforts to establish adoption of, and reimbursement for, OVA1.

***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. General and administrative expenses increased by $126,000, or 5%, for the three months ended June 30, 2011 compared to the same period in 2010. General and administrative expenses for the three months ended June 30, 2011 included increases in legal fees, personnel and personnel-related expenses due to additional headcount compared to the prior year and annual meeting costs incurred in the current period versus the fourth quarter of 2010. The increases were offset by decreases in audit and tax fees incurred in the same period 2010 due to the substantial effort to bring all periodic reports required by the Securities and Exchange Act of 1934 following emergence from bankruptcy.

***Change in fair value and gain from exercise of warrants, net.*** The change in fair value and gain from exercise of warrants was $35,000 for the three months ended June 30, 2011 compared to $3,453,000 for the three months ended June 30, 2010. The decrease of $3,418,000 for the three months ended June 30, 2011 compared to the same period in 2010 was primarily due to the decrease in the Company s stock price during the three months ended June 30, 2010.

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***Reorganization Items.*** Reorganization items for the three months ended June 30, 2011 were $16,000 compared to $265,000 for the same period in 2010. Reorganization items include professional advisory fees and other costs directly associated with the Company s Chapter 11 bankruptcy activities. The activities were largely completed during 2010 resulting in lower expenses during the three months ended June 30, 2011.

***Results of Operations - Six Months Ended June 30, 2011 Compared to Six Months Ended June 30, 2010***

The selected summary financial and operating data of Vermillion for the six months ended June 30, 2011 and 2010 were as follows:

| | Six Months Ended June 30, | | Increase (Decrease) | |
|---|---|---|---|---|
| (dollars in thousands) | 2011 | 2010 | Amount | % |
| Revenue: | | | | |
| Product | $ 508 | $ 45 | $ 463 | 1,029 |
| License | 227 | 372 | (145) | (39) |
| Total revenue | 735 | 417 | 318 | 76 |
| Cost of revenue: | | | | |
| Product | 79 | 12 | 67 | 558 |
| Total cost of revenue | 79 | 12 | 67 | 558 |
| Gross profit | 656 | 405 | 251 | 62 |
| Operating expenses: | | | | |
| Research and development | 2,849 | 1,686 | 1,163 | 69 |
| Sales and marketing | 2,821 | 726 | 2,095 | 289 |
| General and administrative | 5,030 | 4,740 | 290 | 6 |
| Total operating expenses | 10,700 | 7,152 | 3,548 | 50 |
| Loss from operations | (10,044) | (6,747) | (3,297) | 49 |
| Interest income | 37 | 13 | 24 | 185 |
| Interest expense | (230) | (258) | 28 | (11) |
| Change in fair value and gain from exercise of warrants, net | 342 | 3,447 | (3,105) | (90) |
| Debt conversion costs | | (141) | 141 | |
| Reorganization items | (32) | (1,597) | 1,565 | (98) |
| Reorganization items related party incentive plan | | (6,932) | 6,932 | |
| Other income (expense), net | (77) | (69) | (8) | 12 |
| Loss before income taxes | (10,004) | (12,284) | 2,280 | (19) |
| Income tax benefit (expense) | | | | |
| Net loss | $ (10,004) | $ (12,284) | $ 2,280 | (19) |

***Product Revenue.*** Product revenue was $508,000 for the six months ended June 30, 2011 compared to $45,000 for the same period in 2010. The Company performed approximately 7,000 OVA1 tests during the six months ended June 30, 2011 compared to 342 for the same period in 2010. Product revenue increased $463,000 for the six months ended June 30, 2011 compared to the same period in 2010 due to the increased volume of tests as well as the recognition of $160,000 of deferred revenue upon meeting the criteria for revenue recognition.

***License Revenue.*** License revenue was $227,000 for the six months ended June 30, 2011 compared to $372,000 for the same period in 2010. Under the terms of our secured line of credit with Quest, $3,000,000 principal was forgiven upon the achievement of FDA clearance of OVA1. This amount is recognized as license revenue straight-lined over the period of sales exclusivity Quest Diagnostics received beginning on OVA1 s commercialization date of March 9, 2010. License revenue decreased $145,000, or 39%, for the six months ended June 30, 2011 compared to the same period in 2010 due to the extension of the term of exclusivity for up to three additional years in Quest Amendment No. 4. The balance of the $3,000,000 forgiven is being recognized over the revised period of exclusivity.

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***Product Cost of Sales.*** Cost of product revenue includes royalties on net sales paid to JHU, as well as sample acquisition and lot qualification costs related to the testing of reagent lots for the assays included in OVA1 to ensure they meet the specifications required for inclusion. Product cost of sales was $79,000 for the six months ended June 30, 2011 compared to $12,000 for the same period in 2010 due to increased sample acquisition and lot qualification costs as a result of the increased testing volume.

***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 $1,163,000, or 69%, for the six months ended June 30, 2011 compared to the same period in 2010. This increase was due primarily to a $1,352,000 increase in clinical trial and collaboration costs for the ongoing development of our ovarian cancer program and our PAD blood test, VASCLIR, partially offset by decreases in stock-based compensation expense, depreciation expense, and losses on disposal of property and equipment compared to the same period in 2010.

***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 OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and health economic publications. Our personnel-related expenses include the cost of our Territory Development Managers, the subject matter experts responsible for market development and the coordination of interactions with the Quest Diagnostics sales team. Sales and marketing expenses increased by $2,095,000, or 289%, for the six months ended June 30, 2011 compared to the same period in 2010. The increase was primarily due to a $1,437,000 increase in personnel and personnel-related expenses, reflecting 19 sales and marketing related personnel at June 30, 2011 compared to nine sales and marketing related personnel at June 30, 2010. Trade show, advertising and marketing expenses also increased $385,000 related to the continuing cost of OVA1 promotion and education.

***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. General and administrative expenses increased by $290,000, or 6%, for the six months ended June 30, 2011 compared to the same period in 2010. General and administrative expenses for the six months ended June 30, 2011 included increases in stock-based compensation, legal fees, personnel and personnel-related expenses due to additional headcount compared to the prior year and annual meeting costs incurred in the current period versus the fourth quarter of 2010. The increases were offset by decreases in audit and tax fees incurred in the same period 2010 due to the substantial effort to bring all periodic reports required by the Securities and Exchange Act of 1934 following emergence from bankruptcy.

***Change in fair value and gain from exercise of warrants.*** The change in fair value and gain from exercise of warrants was $342,000 for the six months ended June 30, 2011 compared to $3,447,00 for the six months ended June 30, 2010. The decrease of $3,105,000 for the six months ended June 30, 2011 compared to the same period in 2010 was primarily due to the decrease in the Company s stock price during that six months ended June 30, 2010.

***Reorganization items.*** Reorganization items for the six months ended June 30, 2011 totaled $32,000 compared to $1,597,000 for the same period in 2010. Reorganization items include professional advisory fees and other costs directly associated with the Company s Chapter 11 bankruptcy activities. The activities were largely completed during 2010 resulting in lower expenses during the six months ended June 30, 2011.

***Reorganization items - related party incentive plan.*** All Incentive Plan expenses during the six months ended June 30, 2011 were included in general and administrative expense. Reorganization items for the six months ended June 30, 2010 amounted to $6,932,000 and were recorded as Reorganization items-related party incentive plan prior to the Company emerging from bankruptcy in 2010.

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***Liquidity and Capital Resources***

The Company has experienced significant cumulative operating losses since inception and, as of June 30, 2011, had an accumulated deficit of $308,513,000.

On March 9, 2010, we commercially launched OVA1. We will continue to expend substantial resources in the selling and marketing of OVA1, researching and developing additional diagnostic tests, obtaining FDA clearance, and commercializing those products. We will continue to be in an accumulated deficit position unless sufficient revenues can be generated to offset expenses. On February 18, 2011, we completed an underwritten follow-on public offering of our common stock for $21,800,000 in gross proceeds. Net proceeds of the offering were approximately $20,200,000 after deducting underwriting discounts and expected offering expenses. Our $5,000,000 of outstanding 7.00% Notes is due in September 2011. 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/or research and development activities or not be able to pay our existing debt. 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 decisions 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 OVA1.

Cash and cash equivalents as of June 30, 2011 and December 31, 2010, were $36,285,000 and $22,914,000, respectively. Working capital was $25,769,000 and $13,726,000 at June 30, 2011 and December 31, 2010, respectively.

Net cash used in operating activities was $6,771,000 for the six months ended June 30, 2011, resulting primarily from the $10,004,000 net loss incurred as adjusted for a change in fair value of warrants and warrant exercises of $342,000 and non-cash license revenues of $227,000, partially offset by $2,544,000 of stock-based compensation expense. Net cash used in operating activities also included $1,224,000 of cash provided by changes in operating assets and liabilities mainly driven by an increase in accounts payable, accrued liabilities and other liabilities as well as the receipt of $489,000 under the Internal Revenue Service Qualifying Therapeutic Discovery Projects Grant Program for our OVA2 and PAD programs.

Net cash used in operating activities was $14,800,000 for the six months ended June 30, 2010, resulting primarily from operating losses incurred as adjusted for a change in fair value of warrants and warrant exercises of $3,447,000 and non-cash license revenues of $372,000, partially offset by $141,000 of debt issuance costs, $88,000 of depreciation and amortization, $767,000 of stock-based compensation expense and $3,313,000 of accrued incentive plan with related parties. Net cash used in operating activities also decreased by $3,067,000 of cash provided by changes in operating assets and liabilities mainly driven by the $3,353,000 of reorganization items.

Net cash used in investing activities was $93,000 and $90,000 for the six months ended June 30, 2011 and 2010, respectfully, primarily due to the purchase of property and equipment.

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Net cash provided by financing activities was $20,234,000 for the six months ended June 30, 2011, which resulted primarily from net proceeds in connection with our February 2011 follow-on public offering.

Net cash provided by financing activities was $40,030,000 for the six months ended June 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 Diagnostics.

We have significant net operating loss (NOL) credit carryforwards as of December 31, 2010 for which a full valuation allowance has been provided due to our history of operating losses. Our ability to use our net NOL credit carryforwards may be restricted due to ownership change limitations occurring in the past or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. These ownership changes may also limit the amount of NOL credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

We believe that it is probable that an ownership change occurred as a result of our follow-on public offering in February 2011. Any limitation may result in the expiration of a portion of the NOL credit carryforwards before utilization and any NOL credit carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of our valuation allowance. Due to the existence of a valuation allowance, it is not expected that such limitations, if any, will have an impact on our results of operations or financial position.

## 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 June 30, 2011. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2011, our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15(d)-15(e) under the Exchange Act, were effective.

***Changes in internal controls over financial reporting.***

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## PART II - OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

On May 9, 2011, Robert S. Goggins, III ( Goggins ), a stockholder of the Company, filed a complaint in the Court of Chancery of the State of Delaware ( Court of Chancery ), naming the Company and its directors as defendants. In the complaint, Goggins sought to enjoin the 2011 Annual Meeting of Stockholders to take place on June 6, 2011. On May 24, 2011, Goggins filed a motion for preliminary injunctive relief to enjoin the Annual Meeting on June 6, 2011. On June 3, 2011, the Court of Chancery denied the motion and the Annual Meeting was held on June 6, 2011. On June 29, 2011, Goggins filed a notice of voluntary dismissal and the complaint was dismissed.

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 as defendants (the State Court lawsuit ). Under the State Court lawsuit, MAS sought an unspecified amount of damages and alleged, among other things, that we are in breach of a license agreement with MAS relating to the 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 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 we filed a Voluntary Petition for Relief under Chapter 11 in the Bankruptcy Court on March 30, 2009. MAS filed a proof of claim on July 15, 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 our Plan of Reorganization. Per the Court s order confirming the Plan, our 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 the automatic stay so that MAS could proceed with the State Court lawsuit in California. Over our objection, the Bankruptcy Court granted that motion on March 15, 2010. Thereafter, the California Court of Appeal 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 JAMS. MAS filed its demand for arbitration on September 15, 2010. The demand did not include any additional detail regarding MAS s claims, and submitted the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. The parties are currently conducting discovery and the Arbitrator has set September 21, 2011 as the date on which a hearing will commence on MAS s claims. An unfavorable judgement against us could require us to pay monetary damages. Management does not believe an unfavorable outcome is probable, or even reasonably possible for which an amount or range of loss can be estimated such that would require an accrual or disclosure under ASC 450, contingencies; however, 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.

**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, 2010, 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 Our Business**

*We expect to incur a net loss for fiscal 2011. If we are unable to generate significant product and licensing revenue in the future, 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 2011. 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 and bankruptcy under Chapter 11.

*Our ability to commercialize OVA1 and other potential diagnostic tests is heavily dependent on our strategic alliance with Quest Diagnostics.*

Quest Diagnostics has an exclusive license to offer OVA1 in the reference laboratory market as a clinical laboratory test in the US, Mexico, the United Kingdom and India through September 11, 2014, which may be extended for an additional year beyond September 11, 2014. In addition, Quest Diagnostics is expected to have a similar exclusive license with respect to our VASCLIR test for a three year period following clearance by the FDA, as well as with respect to one additional test developed by us, if and to the extent, Quest Diagnostics exercises its development option with respect to any such test on or before October 7, 2012. Consequently, our ability to generate revenue from these tests in these regions is heavily dependent on Quest Diagnostics and its ability to market and offer these tests in its clinical laboratories.

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

We expect that a significant amount of our revenues for the foreseeable future will be derived through our strategic partnership with Quest Diagnostics and will be based on the number of OVA1 tests performed by Quest Diagnostics and the reimbursement rate received by Quest Diagnostics for those tests. On November 10, 2010, we entered into an Amendment No. 4 to our Strategic Alliance Agreement with Quest Diagnostics (the Amendment No. 4 ). Under the terms of the Amendment, we are to be paid $50 for each OVA1 performed by Quest Diagnostics, as well as a 33% royalty of Quest Diagnostics gross margin from performing OVA1 domestically. Amendment No. 4 provides for a monthly payment by Quest Diagnostics to us based on Quest Diagnostics average reimbursement per OVA1 in the previous month. Under the terms of Amendment No. 4, the royalty portion of our revenue is subject to adjustment, either up or down, on an annual basis within 60 days of the end of each calendar year based on Quest Diagnostics actual reimbursement history for that calendar year. To the extent Quest Diagnostics is not reimbursed, is reimbursed at a lower than expected rate, or has reimbursement claims rejected, the royalty amounts owed to us would be reduced. Any amounts owed by us to Quest Diagnostics will be deducted against payments owed to us in future periods. The number of tests performed by Quest Diagnostics and the amount of reimbursement received by Quest Diagnostics in any given period will be largely outside of our control. If Quest Diagnostics were to perform fewer tests or receive less reimbursement per test than expected, it could have a material adverse effect on our revenue and results of operations.

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

As described in detail above, Amendment No. 4 changed the structure and calculation of the payment to be received by us from Quest Diagnostics relating to OVA1. Given our limited commercialization history with OVA1, our lack of experience with the new payment terms contained in Amendment No. 4 and our inability to know or control Quest Diagnostics reimbursement rates for OVA1, it may be difficult for us to estimate the amount of the future revenues and the size of any year-end adjustment. It is likely that we will be unable to recognize some or all of the revenue from the royalty payments to be received from Quest Diagnostics until we are better able to estimate the final royalty payment amounts and the magnitude and effect of the annual recalculation and adjustment mechanism. Accordingly, the amount of revenue we will be able to recognize in any quarter could vary significantly, and the method used to calculate that revenue could be subject to change.

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

A significant portion of our revenues are dependent on the amount Quest Diagnostics receives from third party payers for performing OVA1. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to change and particularly volatile during the early stages of a newly commercialized diagnostic test. OVA1 was commercially launched in March of 2010. There remain questions as to what extent third party payers, like Medicare, Medicaid and private insurance companies will provide coverage for OVA1 and with what limitations. Quest Diagnostics will likely experience volatility in the coverage and reimbursement of OVA1 due to contract negotiations with third party payers and implementation requirements. Quest Diagnostics has advised us that the reimbursement amounts it has received from third party payers varies from payer to payer, and, in some cases, the variation is material. Third party payers, including private insurance companies as well as government payers such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostic test industry. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in the reimbursement rate of payers may occur in the future. Reductions in the price at which OVA1 is reimbursed could have a material adverse effect on our revenues. If we and Quest Diagnostics working collaboratively are unable to establish and maintain broad coverage and reimbursement for OVA1 or if third party payers change their coverage or reimbursement policies with respect to OVA1, our revenues could be materially and adversely affected.

*We may need to raise additional capital in the future beyond what we have raised in a follow-on public offering on February 18, 2011, and if we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our business plan.*

On February 18, 2011, we completed a follow-on public offering of our common stock in which we issued an additional 4 million shares and raised approximately $20.2 million in net proceeds. We believe that our current cash resources will be sufficient to meet our anticipated needs for at least the next twelve months. However, we may need to raise additional capital beyond what we have raised in the follow-on public offering 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 beyond what we have raised in the follow-on offering 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. If we raise additional funds by issuing debt, we may be subject to limitations on our operations, through debt covenants or other restrictions. If we obtain additional funds through arrangements with collaborators or strategic partners, we may be required to relinquish rights to certain technologies or products that we might otherwise seek to retain. If adequate and acceptable financing is not available to us at the time that we seek to raise additional capital, our ability to execute our business plan successfully may be negatively impacted.

*Leverage and debt service obligations may adversely affect our consolidated cash flows.*

As of June 30, 2011, 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 Diagnostics.

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Quest Diagnostics provided us with a $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 under the Bankruptcy Code, certain milestones had been met and the principal balance of the secured line of credit was reduced to $7,000,000. We are in discussions with Quest Diagnostics regarding the achievement of an additional $1,000,000 forgiveness milestone related to OVA1 under the terms of the Amended Strategic Alliance Agreement. 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 principal and interest payment obligations to Quest Diagnostics. 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 our 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 accuracy. It is possible that data from our ongoing PAD intended use study, once received and analyzed, could indicate that the markers will not perform at the same level as in our earlier development studies or at all. Similarly, markers being evaluated for OVA2 may not be validated in downstream pre-clinical or clinical studies, once we undertake and perform such studies.

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, including OVA1, will depend on several factors, including:

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

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

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

Our principal competition currently comes from the many clinical options available to medical personnel involved in clinical decision-making. For example, rather than ordering an OVA1 for a woman with an adnexal mass, obstetricians, gynecologists, and gynecologic oncologists may choose a different clinical option or none at all. If we are not able to convince clinicians that OVA1 provides significant improvement over current clinical practices, our ability to commercialize OVA1 would be adversely affected. In addition, competitors, such as Fujirebio Diagnostics, Inc., Becton Dickinson, ArrayIt Corporation, Correlogic Systems, Inc., HealthLinx, and Abbott Labs 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 assay if and when commercialized could adversely affect our business.

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

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

The FDA cleared OVA1 on September 11, 2009. Our activities related to diagnostic products are, or have the potential to be, subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of our products. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

The Food, Drug and Cosmetic Act requires that medical devices introduced to the United States market, unless exempted by regulation, be the subject of either a pre-market notification clearance, known as a 510(k) clearance or 510(k) de novo clearance, or a PMA. Some of our potential future clinical products may require a 510(k) or 510(k) de novo clearance, while others may require a PMA. With respect to devices reviewed through the 510(k) process, we may not market a device until an order is issued by the FDA finding our product to be substantially equivalent to a legally marketed device known as a predicate device. A 510(k) submission may involve the presentation of a substantial volume of data, including clinical data. The FDA may agree that the product is substantially equivalent to a predicate device and allow the product to be marketed in the United States. On the other hand, the FDA may determine that the device is not substantially equivalent and require a PMA, or require further information, such as additional test data, including data from clinical studies, before it is able to make a determination regarding substantial equivalence. By requesting additional information, the FDA can delay market introduction of our products. Delays in receipt of or failure to receive any necessary 510(k) clearance or PMA approval, or the imposition of stringent restrictions on the labeling and sales of our products, could have a material adverse effect on us. If the FDA indicates that a PMA is required for any of our potential future clinical products, the application will require extensive clinical studies, manufacturing information and likely review by a panel of experts outside the FDA. Clinical studies to support either a 510(k) submission or a PMA application would need to be conducted in accordance with FDA requirements. Failure to comply with FDA requirements could result in the FDA s refusal to accept the data or the imposition of regulatory sanctions. We cannot assure that any necessary 510(k) clearance or PMA approval will be granted on a timely basis, or at all. To the extent we seek FDA 510(k) clearance or FDA pre-market approval for other diagnostic tests, any delay by or failure of the FDA to clear or approve those diagnostic tests may adversely affect our consolidated revenues, results of operations and financial condition.

*If we or our suppliers fail to comply with FDA requirements, 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 could entail additional costs.*

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

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A 510(k) clearance or PMA approval of our device may place substantial restrictions on how our device is marketed or to whom it may be sold. All devices cleared by the FDA are subject to continuing regulation by the FDA and certain state agencies. As a medical device manufacturer, we are also required to register and list our products with the FDA. We are required to set forth and adhere to a Quality Policy and other regulations. In addition, we are required to comply with the FDA s QSRs, which require that our devices be manufactured and records be maintained in a prescribed manner with respect to manufacturing, testing and control activities. Additionally, we may be subject to inspection by federal and state regulatory agencies. Non-compliance with these standards can result in, among other things, fines, injunctions, civil penalties, recalls, total or partial suspension of production. Further, we are required to comply with FDA requirements for labeling and promotion. For example, the FDA prohibits cleared or approved devices from being promoted for uncleared or unapproved uses. Labeling and promotional activities are subject to scrutiny by the FDA, which prohibits the marketing of medical devices for unapproved uses. Additionally, the FDA may has required us to perform certain post-marketing studies ( Post-market Surveillance ) to verify or validate the clinical performance of FDA-cleared tests. These studies will increase our research and development costs.

In addition, the medical device reporting regulation requires that we provide information to the FDA whenever evidence reasonably suggests that one of our devices may have caused or contributed to a death or serious injury, or where a malfunction has occurred that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

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

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

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

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

*We have $7,000,000 outstanding from the secured line of credit provided by Quest Diagnostics. 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 Diagnostics, we will be responsible for full repayment of the secured line of credit on October 7, 2012.*

As of June 30, 2011, 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 Diagnostics has commercially launched three licensed laboratory tests under the Strategic Alliance. On September 11, 2009, we announced our milestone achievement of clearing OVA1 with the FDA and, effective after the emergence from bankruptcy, reduced our principal obligations under the Amended Strategic Alliance Agreement to $7,000,000. We are in discussions with Quest Diagnostics regarding the achievement of an additional $1,000,000 forgiveness milestone related to OVA1 under the terms of the Amended Strategic Alliance Agreement. 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 October 7, 2012, which could materially adversely affect our consolidated results of operations and financial condition.

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

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

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

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

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

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

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

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

An unfavorable judgment against us in any legal proceeding or claim could require us to pay monetary damages. In addition, an unfavorable judgment in which the counterparty is awarded equitable relief, such as an injunction, could have an adverse impact on our licensing and sublicensing activities, which could harm our business, consolidated results of operations and consolidated financial condition.

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 as defendants (the State Court lawsuit ). Under the State Court lawsuit, MAS sought an unspecified amount of damages and alleged, among other things, that we are in breach of a license agreement with MAS relating to the 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 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 we filed a Voluntary Petition for Relief under Chapter 11 in the Bankruptcy Court on March 30, 2009. MAS filed a proof of claim on July 15, 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 our Plan of Reorganization. Per the Court s order confirming the Plan, our 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 the automatic stay so that MAS could proceed with the State Court lawsuit in California. Over our objection, the Bankruptcy Court granted that motion on March 15, 2010. Thereafter, the California Court of Appeal 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 JAMS. MAS filed its demand for arbitration on

September 15, 2010. The demand did not include any additional detail regarding MAS s claims, and submitted the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. The parties are currently conducting discovery and the Arbitrator has set September 21, 2011 as the date on which a hearing will commence on MAS s claims. An unfavorable judgment against us could require us to pay monetary damages. Management does not believe an unfavorable outcome is probable, or even reasonably possible for which an amount or range of loss can be estimated such that would require an accrual or disclosure under ASC 450, contingencies; however, management cannot predict the ultimate outcome of this matter at this time.

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

We are 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. In our bankruptcy proceeding, Bio-Rad filed a claim for approximately $1,000,000. If we are unable to resolve this claim, it would have an adverse effect on our consolidated cash flows.

*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. Any inability to engage new executive officers or key employees could impact operations or delay or curtail our research, development and commercialization objectives. To continue our research and product development efforts, we need people skilled in areas such as clinical operations, regulatory affairs and clinical diagnostics. Competition for qualified employees is intense.

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

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

*Business interruptions could limit our ability to operate our business.*

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

*If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could adversely affect our business, operating results, and financial condition.*

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

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

Compliance with laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, and new regulations adopted by the SEC, are resulting in increased compliance costs. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations. Compliance with these new regulations and disclosure obligations 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% for the years 2011 through 2015. This adjustment is in addition to a productivity adjustment to the Clinical Laboratory Fee Schedule. In addition to the PPACA, the impact of which cannot be predicted given its recent enactment and current lack of implementing regulations or interpretive guidance, a number of states are also contemplating significant reform of their healthcare policies. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation may result in decreased profits to us, and lower reimbursements by payers for our tests, all of which may adversely affect our business.

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

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

**Risks Related to Owning our Stock**

*The liquidity and trading volume of our common stock may be low.*

The liquidity and trading volume of our common stock has at times been low in the past and may again be low in the future. If the liquidity and trading volume were to fall, this could impact the trading price of our shares and adversely affect our ability to issue stock and for holders to obtain liquidity in their shares should they desire to sell.

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

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

- failure to significantly increase revenue;
- actual or anticipated period-to-period fluctuations in financial results;
- failure to achieve, or changes in, financial estimates by securities analysts;
- announcements or introductions of new products or services or technological innovations by us or our competitors;
- publicity regarding actual or potential discoveries of biomarkers by others;
- comments or opinions by securities analysts or 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; and
- economic and other external factors, disasters or crises.

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

*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 intended to give us more leverage to maximize the long term interests of our shareholders in the event of an attempted hostile takeover. While, on balance, the Board of Directors views the benefits to shareholders of these provisions to outweigh their risks, these provisions could delay or prevent a merger, acquisition or other change of control of the Company or limit the price that future investors might be willing to pay for shares of our common stock.

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 we are merged, with a value equal to twice the rights exercise price.

We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company. Under these provisions, if anyone becomes an interested stockholder, we may not enter into a business combination with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change in control of us. An interested stockholder means, generally, someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock during the past three years, subject to certain exceptions as described in the Delaware General Corporation Law.

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

Certain of our stockholders may, from time to time, attempt to aggressively involve themselves in the governance and strategic direction of our Company above and apart from normal interactions between stockholders and management. Such activism, and any related negative publicity, could result in substantial costs that negatively impact our stock price and increase its volatility. In addition, such activism could cause a diversion of the attention of our management and Board of Directors and create perceived uncertainties with existing and potential strategic partners impacting our ability to consummate potential transactions, collaborations or opportunities in furtherance of our strategic plan. In addition, such activism could make it more difficult to attract and retain qualified personnel, customers and business partners, which could disrupt the growth of the market for OVA1, delay the development and commercialization of new tests and further adversely affect the trading price of our common stock and increase its volatility. In addition, the activists may have little or no experience in the diagnostics industry or may seek to elect members to our Board of Directors with little or no experience in the diagnostics industry who may have a specific agenda different and apart from the majority of our stockholders. To the extent any such stockholders constitute a group, as used relating to Section 13 of the Securities Exchange Act of 1934, by having any relationship, agreement, arrangement, affiliation or understanding among themselves, whether direct or indirect, oral or written, specific or informal, it could result in a trigger event under our stockholder rights plan, causing disruption and additional costs to the Company and its stockholders and increasing volatility in our stock 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 beyond what we have raised in a follow-on public offering on February 18, 2011 to meet our capital requirements which could cause significant dilution.*

On February 18, 2011, we completed a follow-on public offering of our common stock in which we issued an additional 4 million shares and raised approximately $20.2 million in net proceeds. As of June 30, 2011, we had 14,811,601 shares of our common stock outstanding and 718,253 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 838,809 shares of our common stock that were subject to outstanding options as well as unvested restricted stock awards. As of June 30, 2011, 206,150 shares of restricted stock awards to certain employees and Directors pursuant to the 2010 Plan remain unvested. These shares vest through March 2014. In addition, as of June 30, 2011, 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 June 30, 2011, 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 our 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.

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

During the three months ended June 30, 2011, we distributed 37,817 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

### ITEM 5. OTHER INFORMATION

On June 17, 2011, we entered into a consulting agreement with Bruce A. Huebner, a member of our Board of Directors. Pursuant to the terms of the consulting agreement, Mr. Huebner is retained as an independent contractor to perform certain consulting services relating to sales, marketing, business development and corporate strategy for us. Mr. Huebner is compensated at the rate of $200 per hour for the consulting services provided, with the total compensation per day not to exceed $1,600.

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**ITEM 6. EXHIBITS**

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

| | |
|---|---|
| 10.1 | Exclusive Distribution Agreement, dated August 1, 2011, by and between Pronto Diagnostics Ltd., and Vermillion, Inc. * |
| 10.2 | Consulting Agreement, dated June 17, 2011, by and between Bruce A. Huebner and Vermillion, Inc. * # |
| 10.3 | Amendment No. 5 to Strategic Alliance Agreement, dated April 2, 2011, by and among Quest Diagnostics Incorporated, Quest Diagnostics India Private Limited and Vermillion, Inc., incorporated by reference to the exhibit 10.1 to the Company s Quarterly Report on Form 10-Q filed on May 10, 2011. |
| 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 * |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.

* Filed herewith.

\# Indicates management contract or compensatory plan.

Confidential treatment has been granted with respect to certain provisions of this agreement. Omitted portions have been filed separately with the SEC.

Certain portions of this exhibit have been omitted and filed separately with the SEC. Confidential treatment has been requested with respect to such omitted portions.

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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: August 9, 2011 | /s/ Gail S. Page<br>Gail S. Page |
| | Executive Chairperson and Chief Executive Officer |
| | (Principal Executive Officer) |
| Date: August 9, 2011 | /s/ Sandra A. Gardiner<br>Sandra A. Gardiner |
| | Vice President and Chief Financial Officer |
| | (Principal Financial Officer) |