VERMILLION, INC.
Form 10-K
March 27, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended December 31, 2011.

¨ **TRANSITION REPORT PURSUANT TO 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)**
Registrant s telephone number, including area code: (512) 519-0400

Securities registered pursuant to Section 12(b) of the Act:

Title of each class to be so registered	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	The NASDAQ Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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 Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K x.

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 ¨	Smaller reporting company x

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 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 ¨

The aggregate market value of voting common stock held by non-affiliates of the Registrant is $45,564,126 and is based upon the last sales price as quoted on The NASDAQ Global Market as of June 30, 2011.

As of February 29, 2012, the Registrant had 14,900,831 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s proxy statement relating to the registrant s 2012 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference into Part III of this Form 10-K where indicated.

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VERMILLION, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2011

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PART I

FORWARD-LOOKING STATEMENTS

Vermillion, Inc. (Vermillion) and its wholly owned subsidiaries (collectively, the Company) has made statements in Part I Item 1, Business ; Part II Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations ; and other sections of this Annual Report on Form 10-K that are deemed forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. We claim the protection of such safe harbor, and disclaim any intent or obligation to update any forward-looking statement. You can identify these statements by forward-looking words such as may, will, expect, intend, anticipate, believe, estimate, plan, could continue or similar words. These forward-looking statements may also use different phrases. We have based these forward-looking statements on management s (we, us or our) current expectations and projections about future events. Examples of language found in forward-looking statements include the following:

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

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

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;

achieving milestones in product development, future regulatory or scientific submissions and presentations;

our plans to develop and commercialize diagnostic tests through our strategic alliance with Quest Diagnostics, Incorporated (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 the OVA1® ovarian tumor triage test (OVA1);

results of clinical trials, post-market studies required by FDA, and publications on OVA1;

our ability to obtain reimbursement from third-party payers for our diagnostic tests, including OVA1;

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

recognition of revenue under our agreement with Quest Diagnostics;

the period of time for which our financial resources will be sufficient to enable us to maintain current and planned operations; and

market risk of our investments.

Such statements are subject to significant risks and uncertainties, including those identified in Part I Item 1A, Risk Factors , that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including our ability to generate sales after completing development of diagnostic products; our ability to manage our operating expenses and cash resources consistently with our plans;

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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; our success in achieving development milestones, achieving desired results in clinical trials or FDA-mandated studies; and our ability to protect and promote our proprietary technologies. We believe it is important to communicate our expectations to our investors. However, there may be events in the future that we are not able to accurately predict or that we do not fully control that could cause actual results to differ materially from those expressed or implied in our forward-looking statements.

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ITEM 1. BUSINESS

Company Overview

We are dedicated to the discovery, development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Our tests are intended to 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 biomarkers into a single, reportable index score that has higher diagnostic accuracy than its constituents. We concentrate our development of novel diagnostic tests in the fields of oncology, cardiology and women s health, with the initial focus on ovarian cancer. We also intend to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and others through collaborations with leading academic and research institutions.

Our lead product, OVA1, was cleared by the United States Food and Drug Administration (FDA) on September 11, 2009. OVA1 addresses a clear unmet clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary FDA-cleared software to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 was developed through large clinical studies in collaboration with numerous academic medical centers encompassing over 2,500 clinical samples. OVA1 was fully validated in a prospective multi-center clinical trial encompassing 27 sites reflective of the diverse nature of the clinical centers at which ovarian adnexal masses are evaluated. The results of the clinical trial demonstrated that in a clinical cohort of 516 patients, OVA1, in conjunction with clinical evaluation, was able to identify 95.6% (154/161) of the malignant ovarian tumors overall, and to rule out malignancy with a negative predictive value (NPV) of 94.6% (123/130). At the 2010 International Gynecologic Cancer Society Meeting, data were presented demonstrating the high sensitivity of OVA1 for epithelial ovarian cancers; OVA1 detected 95/96 epithelial ovarian cancer cases for a sensitivity of 99.0%, including 40/41 stage I and stage II epithelial ovarian cancers, for an overall sensitivity of 97.6% for early stage epithelial ovarian cancers, as compared to 65.9% for CA125 using the American Congress 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 addition to OVA1, we have development programs in other clinical aspects of ovarian cancer as well as in peripheral arterial disease. In the field of peripheral arterial disease, we have identified candidate biomarkers that may help to identify individuals at high risk for a decreased ankle-brachial index score, which is indicative of the likely presence of peripheral arterial disease. We have recently completed an intended-use study to develop and validate a multi-marker algorithm for the assessment of individuals at risk for peripheral arterial disease. This algorithm will be specifically directed at a primary care population in which the peripheral arterial disease blood test (VASCLIR) is expected to be used. Once this study has been published in the peer-reviewed literature, we intend to discuss with the FDA the appropriate submission pathway, which may be Premarket Approval (PMA), 510(k) clearance, or 510(k) de novo clearance. In another program, we have also initiated pilot experiments intended to identify markers with high clinical specificity that may complement OVA1. These experiments are early stage and may take different directions depending on the results. We have yet to establish a regulatory pathway for this potential product (OVA2).

Current and former academic and research institutions that we have or have had collaborations with include the Johns Hopkins University School of Medicine (JHU); the University of Texas M.D. Anderson Cancer Center (M.D. Anderson); University College London (UCL); the University of Texas Medical Branch

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(UTMB); the Katholieke Universiteit Leuven; Clinic of Gynecology and Clinic of Oncology, Rigshospitalet, Copenhagen University Hospital (Rigshospitalet); the Ohio State University Research Foundation (OSU); Stanford University (Stanford); and the University of Kentucky (UK).

We have a strategic alliance agreement (the Strategic Alliance Agreement) with Quest Diagnostics to develop and commercialize up to three diagnostic tests from our product pipeline (the Strategic Alliance). Quest Diagnostics has the exclusive right to commercialize OVA1 until September 2014, with an option to extend such exclusive period in its sole discretion for one additional year. To date, Quest Diagnostics has selected two diagnostic tests to commercialize, VASCLIR and OVA1. On April 2, 2011, we further amended the Strategic Alliance Agreement with Quest Diagnostics and 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. The Amendment also establishes amounts due to Vermillion related to the performance of OVA1 in India.

We were originally incorporated in California on December 9, 1993, under the name Abiotic Systems. In March 1995, we changed our corporate name to Ciphergen Biosystems, Inc. and in May 2000, we reincorporated in Delaware. We had our initial public offering in September 2000. On November 13, 2006, we sold assets and liabilities of our protein research tools and collaborative services business (the Instrument Business Sale), to Bio-Rad Laboratories, Inc. (Bio-Rad), in order to concentrate our resources on developing clinical protein biomarker diagnostic products and services. On August 21, 2007, we changed our corporate name to Vermillion, Inc. On March 30, 2009, we filed a voluntary petition for relief under Chapter 11 of Title 11 of the United States Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (the Bankruptcy Court). Subsequently, on January 22, 2010, the confirmation order issued by the Bankruptcy Court approving our Second Amended Plan of Reorganization under Chapter 11 dated January 5, 2010 became final and all conditions precedent to January 22, 2010 were satisfied or waived. Accordingly, we emerged from bankruptcy protection under Chapter 11 on January 22, 2010. Our Bankruptcy case was formally closed on January 19, 2012.

OVA1 was launched on March 9, 2010 by Quest Diagnostics under the terms of the Strategic Alliance Agreement. On March 11, 2010, the Medicare contractor Highmark Medicare Services announced that it would cover OVA1 in its reimbursement program. On September 20, 2010, we announced that OVA1 was CE marked, a requirement for marketing the test in the European Union. OVA1 has satisfied all certification requirements to complete its declaration of conformity.

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. This supports our goal of expanding OVA1 into international markets.

On November 8, 2011, we entered into an asset purchase agreement with Correlogic Systems, Inc. (Correlogic), pursuant to which and subject to the satisfaction of certain conditions, we agreed to pay to Correlogic $435,000 and purchase from Correlogic substantially all of its assets, including certain documents, diagnostic samples and intellectual property owned by Correlogic in connection with Correlogic s ovarian cancer diagnostics business, including a diagnostic test under the name OvaCheck2 for the detection of ovarian cancer (the Acquisition). Correlogic was in Chapter 11 proceedings in the United States Bankruptcy Court for the District of Maryland (the Court) at the time the asset purchase agreement was entered into and the Acquisition was subject to Court approval. On December 2, 2011, the Court entered an order approving the Acquisition and on December 19, 2011, we completed the Acquisition. We plan to use the Correlogic assets purchased from the Acquisition to advance the goals of our ovarian cancer franchise, including the development of OVA2.

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The Diagnostic Market

The economics of healthcare demand improved allocation of resources which can be derived through disease prevention, early detection of disease leading to early intervention, and diagnostic tools that can triage patients to more appropriate therapy and intervention. According to the May 2009 In Vitro Diagnostics Market Analysis 2009-2024 report, the worldwide market for in vitro diagnostics (IVDs) in 2008 was approximately $40.0 billion. Visiongain, an independent business information provider, predicts that the market will generate nearly $60.0 billion in 2014.

We have chosen to concentrate primarily in the areas of oncology, cardiology and women s health. Demographic trends suggest that, as the population ages, the burden from these diseases will increase and the demand for quality diagnostic, prognostic and predictive tests will increase. In addition, these areas generally lack quality diagnostic tests and, therefore, we believe patient outcomes can be significantly improved by the development of novel diagnostic tests.

Our focus on translational proteomics enables us to address the market for novel diagnostic tests that simultaneously measure multiple protein biomarkers. A protein biomarker is a protein or protein variant that is present at greater or lesser concentrations in a disease state versus a normal condition. Conventional protein tests measure a single protein biomarker whereas most diseases are complex. We believe that efforts to diagnose cancer and other complex diseases have failed in large part because the disease is heterogeneous at the causative level (i.e., most diseases can be traced to multiple potential etiologies) and at the human response level (i.e., each individual afflicted with a given disease can respond to that ailment in a specific manner).

Consequently, measuring a single protein biomarker when multiple protein biomarkers may be altered in a complex disease is unlikely to provide meaningful information about the disease state. We believe that our approach of monitoring and combining multiple protein biomarkers using a variety of analytical techniques will allow us to create diagnostic tests with sufficient sensitivity and specificity about the disease state to aid the physician considering treatment options for patients with complex diseases.

Ovarian Cancer

Background. Commonly known as the silent killer , ovarian cancer leads to approximately 15,000 deaths each year in the United States. Approximately 20,000 new ovarian cancer cases are diagnosed each year, with the majority of the patients in the late stages of the disease in which the cancer has spread beyond the ovary. Unfortunately, ovarian cancer patients in the late stages of the disease have a poor prognosis, which leads to the high mortality rates. According to the American Cancer Society, when ovarian cancer is diagnosed at its earliest stage, the patient has a 5-year survival rate of 93%. Ovarian cancer patients have up to a 90% cure rate following surgery and/or chemotherapy if detected in stage 1. However, only 19% of ovarian cancer patients are diagnosed before the tumor has spread outside the ovary. For ovarian cancer patients diagnosed in the late-stages of the disease, the 5-year survival rate falls to as low as 18%.

While the diagnosis of ovarian cancer in its earliest stages greatly increases the likelihood of survival from the disease, another factor that predicts survival from ovarian cancer is the specialized training of the surgeon who operates on the ovarian cancer patient. Numerous studies have demonstrated that treatment of malignant ovarian tumors by specialists such as gynecologic oncologists or at specialist medical centers improves outcomes for women with these tumors. Published guidelines from the Society of Gynecologic Oncologists (the SGO) and the ACOG recommend referral of women with malignant ovarian tumors to specialists. Unfortunately, today, only about one third of women with these types of tumors are operated on by specialists, in part because of inadequate tests and procedures that can identify such malignancies with high sensitivity. Accordingly, an unmet clinical need is a diagnostic test that can provide adequate predictive value to stratify patients with a pelvic mass into those with a high risk of invasive ovarian cancer versus those with a low risk of ovarian cancer, which is essential for improving overall survival in patients with ovarian cancer.

Although adnexal masses are relatively common, malignant tumors are less so. Screening studies have indicated that the prevalence of adnexal masses in postmenopausal women can be as high as 5 percent. Adnexal

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masses are thought to be even more common in premenopausal women, but there are more non-persistent, physiologic ovarian masses in this demographic. In the Prostate, Lung, Colorectal and Ovarian Cancer study (American Journal of Obstetrics and Gynecology (2005) 193, 1630-9), 28,519 post-menopausal women were screened for ovarian malignancy and 4.7% received an abnormal ultrasound. Using the US census of 53 million women over the age of 50, this suggests there are >2.4 million adnexal masses in this segment alone. Although many of these do not present to the physician or are not concerning enough to warrant surgery, those that do require evaluation for the likelihood of malignancy could potentially benefit from the use of OVA1.

The ACOG and the SGO have issued guidelines to help physicians evaluate adnexal masses for malignancy. These guidelines take into account menopausal status, CA125 levels, and physical and imaging findings. However, these guidelines have notable shortcomings because of their reliance on tools with certain weaknesses. Most notably, the CA125 blood test, which is cleared by the FDA only for monitoring for recurrence of ovarian cancer, is negative in up to 50% of early stage ovarian cancer cases. Moreover, CA125 can be elevated in numerous conditions and diseases other than ovarian cancer, including benign ovarian masses and endometriosis. These shortcomings limit the CA125 blood test s utility in distinguishing benign from malignant ovarian tumors or for use in detection of early stage ovarian cancer. Transvaginal ultrasound is another diagnostic modality used with patients with ovarian masses. Attempts at defining specific morphological criteria that can aid in a benign versus malignant diagnosis have led to the morphology index and the risk of malignancy index, with reports of 40-70% predictive value. However, ultrasound interpretation can be variable and dependent on the experience of the operator. Accordingly, the ACOG and SGO guidelines perform only modestly in identifying early stage ovarian cancer and malignancy in pre-menopausal women. Efforts to improve detection of cancer by lowering the cutoff for CA125 (the Modified ACOG/SGO Guidelines) provide only a modest benefit, since CA125 is absent in about 20% of epithelial ovarian cancer cases and is poorly detected in early stage ovarian cancer.

Clinical Development. To address this documented unmet clinical need, we initiated an ovarian cancer biomarker discovery program. In August 2004, we, along with collaborators at JHU, UCL and M.D. Anderson, reported in a *Cancer Research* paper the discovery of three biomarkers that, when combined with CA125, provided higher diagnostic accuracy for early stage ovarian cancer than other biomarkers, including CA125 alone. The three biomarkers that we reported in the August 2004 *Cancer Research* paper formed the basis of an expanded panel of biomarkers that together have demonstrated risk stratification value in a series of studies involving over 2,500 clinical samples from more than five clinical sites. Data presented at the June 2006 Annual Meeting of the American Society of Clinical Oncology demonstrated the portability of this biomarker panel among different clinical groups, indicating its potential validity across various testing populations. Data presented at the March 2007 Annual Meeting of the SGO described results from a cohort study. We were able to demonstrate in 525 consecutively sampled women, a significant increase in the positive predictive value using its biomarker panel over the baseline level. This translates into the potential to enrich the concentration of ovarian cancer cases referred to the gynecologic oncologist by more than twofold.

OVA1 Ovarian Tumor Triage Test. In January, 2007, we commenced our multi-center prospective clinical trial to demonstrate the clinical performance and utility of OVA1, which was developed based on the studies described above. The clinical study population came from institutions with primary care physicians, gynecologists (non-GO), and/or gynecologic oncologists (GO). The clinical study subject enrollment centers were representative of institutions where ovarian tumor subjects potentially undergo a gynecologic examination. The specimens were collected at 27 demographically mixed sites that included large and small medical centers (universities/community hospitals), clinics that specialize in women s health, small gynecology/obstetrics groups, gynecology/oncology practices, and HMO groups. The performance of OVA1 was determined based on 516 evaluable subjects who underwent surgery to remove a documented ovarian tumor and for whom a pathology result was available. Physicians were asked, based on the information they had, which included physical, radiologic, and laboratory results, whether they believed the patient had cancer (Clinical Assessment). Physicians were not provided with OVA1 score in making this determination. After surgery, the specimen was examined by a surgical pathologist per routine clinical practice. The ability of physicians to predict malignancy without OVA1 was compared to the ability of physicians or OVA1 (Dual Assessment) to predict

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malignancy. With Dual Assessment, which included OVA1, 80.0% of cancers missed by clinician impression alone were detected. Dual Assessment, which included OVA1, had greater sensitivity and negative predictive value than Clinical Assessment alone and the metrics of clinical performance were 91.7% and 93.2%, respectively. We obtained FDA clearance of OVA1 on September 11, 2009. OVA1 is the first FDA-cleared test to be used in the pre-surgical evaluation of ovarian adnexal masses.

Results from the clinical trial were presented at the 2010 Annual Meeting of the SGO. A presentation by Rachel Ware Miller, M.D., Associate Professor of Gynecologic Oncology at the University of Kentucky s Markey Cancer Center, demonstrated that the ACOG/SGO guidelines detected only 77% of ovarian malignancies and that the Modified ACOG/SGO Guidelines improved detection to only 80%. Moreover, detection of early stage ovarian cancer was only 47%. A second presentation by Fred Ueland, M.D., Associate Professor of Gynecologic Oncology, demonstrated that among non-gynecologic oncologists, OVA1, in conjunction with clinical impression, improved detection of malignancy to 92% from 72% using clinical impression alone among patients evaluated by non-gynecologic oncologists. Among these patients, detection of stage I ovarian cancer was 79%.

Additional results from the clinical trial were presented at the 2010 International Gynecologic Cancer Society (IGCS) meeting. This presentation reported that OVA1 had overall sensitivity for ovarian cancer of 92.5%, as compared to 68.9% for CA125 using cutoffs established in the ACOG criteria for adnexal mass evaluation and 77.0% for CA125 using cutoffs in the modified ACOG criteria. Additionally, data were presented demonstrating the high sensitivity of OVA1 for epithelial ovarian cancers; OVA1 detected 95/96 epithelial ovarian cancer cases for a sensitivity of 99.0%, including 40/41 stage I and stage II epithelial ovarian cancers, for an overall sensitivity of 97.6% for early stage epithelial ovarian cancers, as compared to 65.9% for CA125 using the 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.

Health economic analysis indicates that anticipated benefits of OVA1 include i) more appropriate referrals of women with high risk of malignancy to a gynecologic oncologist and fewer referrals of women at low risk of malignancy; ii) fewer second surgeries as a result of an initial surgery by a generalist on a woman with a malignant tumor; iii) reduced need for a backup surgeon (i.e. specialist) during a surgery by a generalist; iv) more appropriate and efficient administration of intraperitoneal chemotherapy; v) longer survival, associated with better quality of life.

Peripheral Arterial Disease

Peripheral arterial disease (PAD) represents atherosclerosis of the lower extremities and is generally reflective of systemic atherosclerotic disease and is therefore a risk factor for adverse cardiac events such as myocardial infarction and stroke. This disease affects between 8-12 million Americans, and the number of people diagnosed with PAD is expected to increase concurrently with the rising number of people diagnosed with diabetes. The American Heart Association and the American College of Cardiology have identified three demographics at risk for PAD: smokers 50 years of age or older; diabetics 50 years of age or older; and the elderly 65 years of age or older. Collectively, this represents tens of millions of Americans.

PAD is most commonly diagnosed using the ankle-brachial index (ABI), which is performed using a handheld Doppler. Blood pressures are measured in the arm and at the ankles and the ratio (ankle/arm) is calculated. Non-affected individuals should have a ratio of 0.9 or greater, while individuals with a ratio of less than 0.9 are defined as having PAD. Although the ABI has good sensitivity and specificity for PAD, its implementation into routine clinical practice has been hampered by poor physician adoption, generally because of the need to utilize special equipment by a specially trained technician and the need to have the patient lie supine in an examination room for 10 to 30 minutes prior to the administration of this test. Additionally, studies

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have shown that the ABI is often performed incorrectly. Therefore, a blood test that can be more routinely implemented would be beneficial in identifying people at increased risk for PAD.

In collaboration with John P. Cooke, M.D., Ph.D., a Professor and Associate Director of the Stanford Cardiovascular Institute at Stanford University School of Medicine, we have performed both an initial discovery study and a first validation study that has resulted in the identification of blood markers that could assist in the diagnosis of PAD. These findings form the basis of a novel blood diagnostic test for PAD.

The results of these studies, including the publication of two blood markers for PAD, were published in the August 2007 on-line issue of the peer-reviewed journal Circulation, which is published by the American Heart Association (the AHA). Independent validation of these initial findings was subsequently published in the peer-reviewed journal Vascular Medicine in 2008. This study, which encompassed 540 individuals, confirmed the elevation of the two biomarkers in subjects with PAD. Moreover, the study showed that a panel of markers improved the identification of subjects with PAD and was complementary to available data, including the AHA risk score. In this study, subjects with a moderate AHA risk score but elevated PAD biomarker score had almost a 7 times increased likelihood of having PAD than if they had a normal PAD biomarker score.

Commercialization

We expect to commercialize and sell diagnostic tests (which may consist of reagents and/or proprietary software) in one or both of two phases. One phase, referred to as the laboratory developed test (LDT) phase, will involve the sale of certain reagents (which may be in the form of proprietary software) to certain customers coupled with the grant to such customer of a sublicense to utilize the reagent in a laboratory-developed test using the methodology covered by the relevant license(s) obtained from our collaborators. An LDT would comprise multiple reagents (such as assay test kits, software, or other reagents), some of which would be supplied by us, and would be utilized by clinical laboratories to develop and perform home brew laboratory tests in laboratories federally regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In the other phase, referred to as the IVD phase, we plan to sell FDA-cleared devices (which may comprise multiple reagents such as assay test kits, software, or other reagents).

Under the terms of the Amended Strategic Alliance Agreement, Quest Diagnostics has the right to commercialize up to three diagnostic tests from our product pipeline. To date, Quest Diagnostics has selected two tests, VASCLIR and OVA1. Pursuant to the Amended Strategic Alliance Agreement, Quest Diagnostics will have the non-exclusive right to commercialize each of the tests other than OVA1 on a worldwide basis, with exclusive commercialization rights in each exclusive territory, as this term is defined in the Amended Strategic Alliance Agreement, beginning on the date each test is first commercialized and ending on the third anniversary of the date that such test is cleared or approved by the FDA. Quest has exclusive commercialization rights to commercialize OVA1 in each exclusive territory through September 2014 and the right to extend the exclusivity period for one additional year. These exclusive territories consist of the United States, India, Mexico, and the United Kingdom. Quest Diagnostics has the non-exclusive right to commercialize OVA1 on a worldwide basis outside of these exclusive territories.

Customers

In the United States, the IVD market can be segmented into three major groups: clinical reference laboratories, the largest of which are Quest Diagnostics and Laboratory Corporation of America; hospital laboratories; and physician offices. Initially, substantially all of our revenue in the United States will be generated through clinical reference laboratories, and Quest Diagnostics will be the major customer. We will attempt to penetrate hospital laboratories and physician offices, when appropriate. Outside the United States, laboratories may become customers, either directly with us or via distribution relationships established between us and authorized distributors.

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Research and Development

Our research and development efforts center on the discovery and validation of biomarkers and combinations of biomarkers that can be developed into diagnostic assays. We do this predominantly through collaborations we have established with academic institutions such as JHU, Rigshospitalet, and Stanford as well as through contract research organizations (CRO s) such as PrecisionMed and the Colorado Prevention Center.

Scientific Background

Genes are the hereditary coding system of living organisms. Genes encode proteins that are responsible for cellular functions. The study of genes and their functions has led to the discovery of new targets for drug development. Industry sources estimate that, within the human genome, there are approximately 30,000 genes. Although the primary structure of a protein is determined by a gene, the active structure of a protein is frequently altered by interactions with additional genes or proteins. These subsequent modifications result in hundreds of thousands of different proteins. In addition, proteins may interact with one another to form complex structures that are ultimately responsible for cellular functions.

Genomics allows researchers to establish the relationship between gene activity and disease. However, many diseases are manifested not at the genetic level, but at the protein level. The complete structure of modified proteins cannot be determined by reference to the encoding gene alone. Thus, while genomics provides some information about diseases, it does not provide a full understanding of disease processes. We are focused on converting recent advances in proteomics into clinically useful diagnostic tests.

Relationship Between Proteins and Diseases

The entire genetic content of any organism, known as its genome, is encoded in strands of deoxyribonucleic acid (DNA). Cells perform their normal biological functions through the genetic instructions encoded in their DNA, which results in the production of proteins. The process of producing proteins from DNA is known as gene expression or protein expression. Differences in living organisms result from variability in their genomes, which can affect the types of genes expressed and the levels of gene expression. Each cell of an organism expresses only approximately 10% to 20% of the genome. The type of cell determines which genes are expressed and the amount of a particular protein produced. For example, liver cells produce different proteins from those produced by cells found in the heart, lungs, skin, etc. Proteins play a crucial role in virtually all biological processes, including transportation and storage of energy, immune protection, generation and transmission of nerve impulses and control of growth. Diseases may be caused by a mutation of a gene that alters a protein directly or indirectly, or alters the level of protein expression. These alterations interrupt the normal balance of proteins and create disease symptoms. A protein biomarker is a protein or protein variant that is present in a greater or lesser amount in a disease state versus a normal condition. By studying changes in protein biomarkers, researchers may identify diseases prior to the appearance of physical symptoms. Historically, researchers discovered protein biomarkers as a byproduct of basic biological disease research, which resulted in the validation by researchers of approximately 200 protein biomarkers that are being used in commercially available clinical diagnostic products.

Limitations of Existing Diagnostic Approaches

The IVD industry manufactures and distributes products that are used to detect thousands of individual components present in human derived specimens. However, the vast majority of these assays are used specifically to identify single protein biomarkers. The development of new diagnostic products has been limited by the complexity of disease states, which may be caused or characterized by several or many proteins or post-translationally modified protein variants. Diagnostic assays that are limited to the detection of a single protein often have limitations in clinical specificity (true negatives) and sensitivity (true positives) due to the complex nature of many diseases and the inherent biological diversity among populations of people. Diagnostic products that are limited to the detection of a single protein may lack the ability to detect more complex diseases, and thus produce results that are unacceptable for practical use. The heterogeneity of disease and of the human response to disease often underlies the shortcoming of single biomarkers to diagnose and predict many diseases accurately.

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Our Solution

Our studies, particularly in ovarian cancer, have given us a better understanding of both the disease pathophysiology and the host response. By using multiple biomarkers, we are able to better characterize the disease and host response heterogeneity. In addition, by examining specific biomarkers with greater resolution, for example, post-translational modifications, we believe we can improve the specificity of our diagnostic biomarkers because these modifications reflect both the pathophysiology and host response. This is accomplished using novel protein analysis tools coupled with multivariate statistical analysis software to identify combinations of specific biomarkers leading to commercialization of disease-specific assays.

We are applying translational proteomics research, development tools, and methods to analyze biological information in an attempt to discover associations between proteins, protein variants, protein-protein interaction and diseases. We intend to develop new diagnostic tests based on known and newly identified protein markers to help physicians predict an individual s predisposition for a disease in order to better characterize, monitor progression of and select appropriate therapies for such disease. Our goal is to develop novel diagnostic tests that address unmet medical needs, particularly in stratifying patients according to the risk of developing a disease, having a disease or failing a specific therapy for a disease.

Addressing the Heterogeneity of Disease

Our strategy is to create a diagnostics paradigm that is based on risk stratification, multiple-biomarker testing and information integration. This strategy is based on the belief that any specific disease is heterogeneous and, therefore, relying on a single disease biomarker to provide a simple yes-no answer is likely to fail. We believe that efforts to diagnose cancer and other complex diseases have failed in large part because the disease is heterogeneous at the causative level, meaning that most diseases can be traced to multiple potential etiologies, and at the human response level, meaning that each individual afflicted with a given disease can respond to that ailment in a specific manner. Consequently, diagnosis, disease monitoring and treatment decisions can be challenging. This heterogeneity of disease and difference in human response to disease and/or treatment underlies the shortcomings of single biomarkers to predict and identify many diseases. A better understanding of heterogeneity of disease and human response is necessary for improved diagnosis and treatment of many diseases.

Validation of Biomarkers Through Proper Study Design

Analysis of peer-reviewed publications reveals almost daily reports of novel biomarkers or biomarker combinations associated with specific diseases. Few of these are used clinically. As with drug discovery, preliminary research results fail to canvass sufficient variation in study populations or laboratory practices and, therefore, the vast majority of candidate biomarkers fail to be substantiated in subsequent studies. Recognizing that validation is the point at which most biomarkers fail, our strategy is to reduce the attrition rate between discovery and clinical implementation by building validation into the discovery process. Biomarkers fail to validate for a number of reasons, which can be broadly classified into pre-analytical and analytical factors. Pre-analytical factors include study design that does not mimic actual clinical practice, inclusion of the wrong types of control individuals and demographic bias (usually seen in studies in which samples are collected from a single institution). Analytical factors include poor control over laboratory protocols, inadequate randomization of study samples and instrumentation biases (for example, higher signal early in the experimental run compared to later in the experimental run). Finally, the manner in which the data are analyzed can have a profound impact on the reliability of the statistical conclusions.

When designing clinical studies, we begin with the clinical question, since this drives the downstream clinical utility of the biomarkers. With the starting point of building validation into the discovery process, we design our studies to include the appropriate cases and control groups. We further incorporate an initial validation component even within the discovery component. We place an emphasis on multi-institutional studies,

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inclusion of clinically relevant controls, using qualified and trained operators to run assays and collect data. For example, in an August 2004 cancer research paper, which describes the first three biomarkers in the ovarian cancer panel, there were more than 600 specimen samples taken from five hospitals that were analyzed. In the development of OVA1, we analyzed more than 2,500 samples from five additional medical centers prior to initiating the prospective ovarian clinical study for submission to the FDA. Additionally to date, we have examined over 600 samples in our PAD program. In analyzing the complex proteomics data, we take a skeptical view of statistical methodologies, choosing to use a variety of approaches and looking for concordance between approaches, taking the view that biomarkers deemed significant by multiple statistical algorithms are more likely to reflect biological conditions than mathematical artifacts.

Through biomarker discovery efforts conducted predominantly from 2000 through 2007, we have amassed a portfolio of candidate biomarkers identified in retrospective sample sets. Our research and development efforts are now mostly focused on validating these biomarkers in prospective studies. During the period from 2007 through 2008, we conducted a multi-center prospective clinical trial to determine the clinical performance of OVA1, which was submitted to the FDA on June 19, 2008, and cleared by the FDA on September 11, 2009. We have additional markers for ovarian cancer that we plan to evaluate and validate. Additionally, we recently completed a prospective intended use study for PAD. These activities are outlined below.

R&D-sponsored initiatives to support market development to support OVA1

We have two ongoing R&D-sponsored initiatives to support OVA1 market development and adoption as an improved standard of care in the pre-surgical triage and evaluation of adnexal masses. The first is a major new clinical study of OVA1, focused on its performance in the predominantly pre-menopausal non-Gynecologic Oncologist patient population. This will follow up on and extend the landmark studies of Ueland and Miller with a completely new patient cohort, in an independent, multi-center patient population. We expect this study to be submitted later in 2012 for publication.

The second is a series of Vermillion-assisted, independent clinical research studies of OVA1. Through this new program, Vermillion offers limited support for well-qualified Principal Investigators in the form of materials, testing services, and scientific consulting. As a result, we are currently in discussion with a number of potential investigators, to support new research publications on OVA1 s clinical utility, cost-effectiveness, and potential line extensions.

New ovarian cancer indications. While our focus on supporting the commercialization of OVA1 is our primary priority, we also may extend our ovarian cancer franchise beyond OVA1, enabled by three key initiatives. First, we have a research and license agreement with JHU to evaluate markers that provide improved specificity in the detection of ovarian cancer. Candidate markers are currently being assessed in small, pilot sample sets. Markers demonstrating high specificity may then be assessed in larger, clinical samples sets. Pilot results of these studies were reported in early 2011 at the Society of Gynecologic Oncologists. Second, our research and license agreement with Rigshospitalet (Copenhagen) generated data showing that a certain combination of markers can separate ovarian cancer patients into those with good prognosis from those with poor prognosis. These results were published in 2010 and we filed a patent application. Third, the acquisition of Correlogic assets in 2011 brings with it highly curated clinical samples, intellectual property and promising biomarker leads. These have the potential to further amplify our OVA2 efforts in the future.

Prospective intended-use clinical study for Peripheral Arterial Disease (PAD). In 2011, we completed an intended-use study to validate a multi-marker algorithm for the assessment of individuals at risk for PAD. This algorithm will be specifically directed at a primary care population in which VASCLIR is expected to be used.

The intended use study was a prospective, double-blinded multi-center study of approximately 1,000 subjects who met specific inclusion criteria for being at increased risk of having PAD, including smokers and diabetics age 50 or above and elderly age 70 or above. On October 3, 2011, we announced positive top-line

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results from the intended use study of VASCLIR. The goals of the study were to validate the markers described in earlier publications (*Circulation*, 2007 and *Vascular Medicine*, 2008) and to develop and validate a biomarker panel applicable to the intended use population.

Key results of the study include the following:

- The individual biomarkers beta-2 microglobulin (B2M), cystatin C, and hsCRP (high sensitivity c-reactive protein), each had statistically significant different levels between PAD subjects and non-PAD subjects (p<.001).

- As in the previous study described in the earlier publications, these biomarkers showed statistically significant correlation to the ankle-brachial index or ABI, (p<.001).

- A logistic regression model was able to identify more than 80% of PAD patients among those deemed low-risk by the conventional Framingham Risk Score for estimating cardiovascular disease probability.

The work has been submitted for presentation at a recognized national vascular medicine conference, and is awaiting a decision. A manuscript will also be submitted to a leading vascular medicine journal in the first half of 2012. This presentation and manuscript will support our future discussions with the FDA regarding the appropriate submission pathway, which may be PMA, 510(k) clearance, or 510(k) de novo clearance. Quest Diagnostics has accepted the PAD test as a development program under the terms of the Amended Strategic Alliance Agreement.

Our research and development expenses were $5,387,000 and $3,848,000 for the years ended December 31, 2011 and 2010, respectively.

Commercial Operations

We have a commercial infrastructure, including sales and marketing and reimbursement expertise. Our sales representatives work with colleagues at Quest Diagnostics to identify opportunities for communicating the benefits of OVA1 to general gynecologists and gynecologic oncologists alike. Our success will also depend on our ability to penetrate markets outside of the United States. OVA1 is CE marked, a requirement for marketing the test in the European Union. OVA1 has satisfied all certification requirements to complete its declaration of conformity.

At the end of 2011, approximately 15,225 OVA1 tests had been performed in the calendar year, an increase of 147% over 2010. Additionally, over 275 gynecologic oncologists are supportive or advocating the use of OVA1 for the triage of women with adnexal masses. This broad number of specialists supporting the test indicates an understanding of the unmet clinical need and the ability of OVA1 to serve a significant market to assist physicians to triage women who need a specialist for surgery from those who can be treated by the primary physician. As of December 2011, 3,700 doctors had ordered OVA1, an increase of 153% over December 2010. This indicates a market penetration of 11% of the available gynecologists in the US.

We continue to develop the market through experienced Territory Development Managers and have expanded their scope of responsibility. As market awareness continues to build, these managers are focused on efforts that will have a positive impact on regional payers and create positive coverage decisions. They are working with local key opinion leaders and meeting with medical directors to discuss the unmet clinical need, our technology assessment package and increasing experience and cases studies showing the positive outcomes utilizing OVA1.

There are still obstacles to overcome and significant milestones to attain to ensure ongoing success. First, although the test volume and the number of doctors continue to increase, the average gynecologist will only see about 2 to 4 appropriate patients per month and additional effort will be required to establish a consistent

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ordering pattern. Second, insurance coverage and patient bills are a concern to the physician and can disrupt the ordering pattern of a generalist who is supportive of OVA1. These obstacles are being addressed in a cross functional approach to include publishing additional clinical studies, working towards OVA1 inclusion in professional guidelines in a reasonable time frame, adding positive coverage decisions on a regional and national basis, and improving coding and claims through obtaining a Category I CPT code.

In January 2012, we announced a restructuring plan to streamline our organization and reduce our cash expenditures compared to 2011. This plan included eliminating the positions of Chief Financial Officer and Vice President of Corporate Strategy as well as a reduction in our Territory Development and sales management personnel. We intend to reduce cash-based operating expenses in 2012; extending our cash runway while focusing our efforts on the continued commercialization of OVA1 and advancing our product pipeline.

Reimbursement

In the United States, revenue for diagnostic tests comes from several sources, including third-party payers such as insurance companies and government healthcare programs, such as Medicare and Medicaid. On March 12, 2010, we announced that Highmark Medicare Services, the Medicare contractor that has jurisdiction over claims submitted by Quest Diagnostics for OVA1, will cover OVA1. This local coverage determination from Highmark Medicare Services essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. We have worked together with Quest Diagnostics to obtain coverage and reimbursement from private payers across the country. As of January 1, 2012, twenty-five independent BlueCross BlueShield plans, representing more than 41 million lives, provide coverage for OVA1. In total, including Medicare and other private payers, approximately 88 million patients have access and coverage for OVA1. The Company and Quest Diagnostics are pursuing coverage from additional payers.

On March 6, 2012, the American Medical Association (AMA) Current Procedural Terminology (CPT®) Panel voted to approve an application for a Category I CPT code for OVA1. The AMA recently disclosed the new code on its website, which will become effective January 1, 2013. The new CPT code is a positive step forward in advancing the commercialization of OVA1, as we believe it will help streamline claims processing and accelerate further coverage and adoption by private payers.

New and innovative diagnostic tests often face reimbursement challenges that can affect adoption; the three key focus areas are coding, claims, and coverage or payor adoption. In conjunction with Quest Diagnostics, we are consistently addressing these three areas.

Coding-

OVA1 is a new class of diagnostics and therefore no specific code existed upon our launch. This is often the case with new diagnostic tests and companies will bill using a miscellaneous code, which is the path we and Quest Diagnostics have implemented. Now, after establishing OVA1 in the market, creating demand, demonstrating the utility of the test, obtaining coverage and reimbursement, we took the additional step of filing for a CPT code specific for OVA1 in 2011.

Achieving a unique Category I Code is a critical step in a company s commercialization process.

Now that our CPT code has been approved, the process will continue forward to establish the appropriate reimbursement rate for the unique code.

Claims Process

In the early launch of a product that does not have its own CPT code, claims can be rejected due to lack of medical necessity, lack of payer understanding, or even billing process errors. To address these items, our Territory Development Managers are engaging with physicians offices to assist in the appeals process and are using these claims to educate payers and create awareness about the medical necessity of our test.

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Payer Coverage

- We continue to focus on going efforts toward obtaining national coverage decisions. However, these typically have a much longer lead time due to industry established processes and time frames. In most cases, these entail clinical and technical reviews that are performed on an annual basis.
- We have assembled a Technology Assessment Package that will provide a nucleus of materials tailored to each National Plan.
- We have launched a program to aid local key opinion leaders to work with health plans to support coverage for OVA1. These strategic actions are necessary steps to convert those plans representing numerous regional payers and late adopters.

Competition

The diagnostics industry in which we operate is competitive and evolving. There is intense competition among healthcare, biotechnology and diagnostics companies attempting to discover candidates for potential new diagnostic products. These companies may:

- develop new diagnostic products in advance of us or our collaborators;
- develop diagnostic products that are more effective or cost-effective than those developed by us or our collaborators;
- obtain regulatory clearance or approval of their diagnostic products more rapidly than us or our collaborators; or
- obtain patent protection or other intellectual property rights that would limit the ability to develop and commercialize, or a customers ability to use our or our collaborators diagnostic products.

We compete with companies in the United States and abroad that are engaged in the development and commercialization of novel biomarkers that may form the basis of novel diagnostic tests. These companies may develop products that are competitive with and/or perform the same or similar to the products offered by us or our collaborators, such as biomarker specific reagents or diagnostic test kits. Also, clinical laboratories may offer testing services that are competitive with the products sold by us or our collaborators. For example, a clinical laboratory can either use reagents purchased from manufacturers other than us or use its own internally developed reagents to make diagnostic tests. If clinical laboratories make tests in this manner for a particular disease, they could offer testing services for that disease as an alternative to products sold by us used to test for the same disease. The testing services offered by clinical laboratories may be easier to develop and market than test kits developed by us or our collaborators because the testing services are not subject to the same clinical validation requirements that are applicable to FDA-cleared or approved diagnostic test kits.

In September 2011, Fujirebio Diagnostics received FDA clearance for Risk of Ovarian Malignancy Algorithm. This test is made up of two tumor markers (HE4 and CA125II) and includes a publicly available algorithm which takes into consideration menopausal status. The intended use is the same as OVA1. In January 2012, the test was made available by Laboratory Corporation of America.

The two tests have not been compared in a side by side cohort evaluation to date, so no direct performance comparisons can be made. However, studies have shown OVA1 offers significant performance in the following key areas:

- 96% sensitivity across a broad range of Ovarian Cancer subtypes;

98% sensitivity for early stage epithelial ovarian cancer;

95% NPV adds reassurance that an ovarian mass with a negative OVA1 score is benign; and a

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comprehensive 5 biomarker panel that detects tumor secreted proteins while also measuring the host response to ovarian cancer The market has indicated that these factors are critical to the proper triage of women with ovarian masses.

Intellectual Property Protection

Our intellectual property includes a portfolio of owned, co-owned or licensed patents and patent applications. As of December 31, 2011, our patent portfolio included 52 issued United States patents, 93 pending United States patent applications, and numerous pending patent applications and issued patents outside the United States. These patents and patent applications are directed to several areas of technology important to our business, including our Surfaced Enhanced Laser Desorption/Ionization (SELDI) technology, diagnostic applications, protein biochips, instrumentation, software and biomarkers. The issued patents covering the SELDI and mass spectrometry technologies expire at various times from 2012 to 2025. As part of the Instrument Business Sale, we entered into a cross license agreement with Bio-Rad pursuant to which we retained the right to commercially exploit those proprietary rights, including SELDI technology, in the clinical diagnostics market. The clinical diagnostics market includes laboratories engaged in the research and development and/or manufacture of diagnostic tests using biomarkers, commercial clinical laboratories, hospitals and medical clinics that perform diagnostic tests. We have been granted exclusive rights to commercialize the proprietary rights in the clinical diagnostics market during a five-year exclusivity period that ended on November 13, 2011. After the end of the five-year period, we now share exclusive rights with Bio-Rad. The Company and Bio-Rad each have the right to engage in negotiations with the other party for a license to any improvements in the proprietary rights created by the other party.

We own, license or hold options to license the patents related to biomarkers developed using SELDI technology. As of December 31, 2011, we were maintaining and/or had license to 26 diagnostic patent application families. These include applications in the areas of cancer, cardiovascular disease, infectious disease, neurodegenerative disease and women s health. On March 31, 2009, we were issued patent number 7,510,842, Biomarker for ovarian and endometrial cancer: hepcidin . On October 20, 2009, we were issued patent number 7,605,003, Use of biomarkers for detecting ovarian cancer . On June 29, 2010, we announced that the United States Patent and Trademark Office (USPTO) has issued a notice of allowance to us of a patent entitled Biomarkers for Alzheimer s disease . On January 11, 2011, we were issued patent number 7,867,719 entitled Beta-2 microglobulin as a biomarker for peripheral artery disease . The patent claims are directed to beta-2 microglobulin and biomarker combinations that include Beta-2 microglobulin for the diagnosis and management of peripheral artery disease and to the measurement of the biomarkers by a variety of methods, including mass spectrometry and immunoassay. On February 2, 2011, we announced that the USPTO had issued a notice of allowance to us of a patent entitled Biomarkers for breast cancer. On May 17, 2011, we announced that the 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 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 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. On September 6, 2011, we announced that theUSPTO has issued patent number 8,014,952 entitled Serum Biomarkers in Lung Cancer to the Company. On November 3, 2011, we announced the receipt of a notice of allowance from the USPTO for our

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fifth patent covering a combination of biomarkers that could be used in the diagnosis of PAD, a condition that raises the risk of heart attack and stroke. The patent, entitled Beta-2 Microglobulin (B2M) and C Reactive Protein (CRP) as Biomarkers for Peripheral Artery Disease, involves a unique combination of B2M and CRP, two proteins that have been demonstrated in numerous studies to be associated with PAD.

On December 19, 2011, we completed the purchase of substantially all of the assets associated with the ovarian cancer diagnostics business of Correlogic for $435,000 in cash. The assets include more than 1,800 prospectively collected diagnostic samples from ovarian tumor studies, three biomarker-related pending U.S. patents, proprietary software and other intellectual property.

On March 5, 2012 we announced the receipt of a notice of allowance from the USPTO for Platelet biomarkers for cancer. The patent resulted from a collaboration with the late Dr. Judah Folkman, a renowned cancer expert, and identifies three biomarkers that can be used to assess changes in endogenous angiogenesis in a subject. Angiogenesis is commonly associated with cancer, and novel therapeutics such as bevacizumab (Avastin®) target angiogenesis to limit tumor recruitment of blood vessels. The patented biomarkers, which are associated with platelets, can be used to measure ongoing angiogenic activity. The patent covers the measurement of these biomarkers over time and correlating changes in expression with the changing level of endogenous angiogenic activity. Consequently, this patent also enables the use of these biomarkers to monitor efficacy of therapy directed at angiogenic pathways.

Under the terms of an amended research collaboration agreement with the Johns Hopkins University School of Medicine, we are required to pay JHU $400,000 for 2012 and $100,000 for 2013. Collaboration costs under the JHU collaboration were $235,000 and $400,000 for the years ended December 31, 2011 and 2010, respectively. 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 $52,500. Other institutions and companies from which we hold options to license intellectual property related to biomarkers or are a co-inventor on applications include UCL, M.D. Anderson, UK, OSU, McGill University (Canada), Eastern Virginia Medical School, Aaron Diamond AIDS Research Center, UTMB, Goteborg University (Sweden), University of Kuopio (Finland), The Katholieke Universiteit Leuven (Belgium) and Rigshospitalet.

In connection with the Instrument Business Sale, we sublicensed to Bio-Rad certain rights to the core SELDI technology for use outside of the clinical diagnostics field. We retained exclusive rights to the license rights for use in the field of clinical diagnostics for a five-year period, after which the license became co-exclusive in this field. The rights to the SELDI technology are derived through royalty-bearing sublicenses from Molecular Analytical Systems, Inc. (MAS). MAS holds an exclusive license to patents directed to the SELDI technology from the owner, Baylor College of Medicine. MAS granted certain rights under these patents to its wholly owned subsidiaries, IllumeSys Pacific, Inc. and Ciphergen Technologies, Inc. in 1997. We obtained further rights under the patents in 2003 through sublicenses and assignments executed as part of the settlement of a lawsuit between us, MAS, LumiCyte and T. William Hutchens. Together, the sublicenses and assignments provide all rights to develop, make and have made, use, sell, import, market and otherwise exploit products and services covered by the patents throughout the world in all fields and applications, both commercial and non-commercial. The sublicenses carry the obligation to pay MAS a royalty equal to 2% of revenues recognized between February 21, 2003, and the earlier of (i) February 21, 2013, or (ii) the date on which the cumulative payments to MAS have reached $10,000,000 (collectively, the Sublicenses).Under our sublicense with Bio-Rad, Bio-Rad agreed to pay the royalties directly to MAS under the license rights.

Manufacturing

We are the manufacturer of OVA1. Components of OVA1 include reagents for each of the component assays as well as the OvaCalc® software. Because we do not directly manufacture the component assays, we are

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required to maintain supply agreements with manufacturers of each of the assays. As part of our Quality Systems, reagent lots for these assays are tested to ensure they meet specifications required for inclusion in OVA1. Only reagent lots determined by us as having met these specifications are permitted for use in OVA1.

Environmental Matters

Medical Waste

We have been subject to licensing and regulation under federal, state and local laws relating to the handling and disposal of medical specimens and hazardous waste as well as to the safety and health of laboratory employees. We formerly operated laboratories located in each of our former facilities in Fremont, California, the last lease for which expired on August 31, 2010. Our laboratories were operated in material compliance with applicable federal and state laws and regulations relating to disposal of all laboratory specimens. We utilized outside vendors for disposal of specimens. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use, or the use by third parties, of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts.

Occupational Safety

In addition to its comprehensive regulation of safety in the workplace, the Federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to chemicals and transmission of the blood-borne and airborne pathogens. Although we believe that we are currently in compliance in all material respects with such federal, state and local laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

Specimen Transportation

Regulations of the Department of Transportation, the International Air Transportation Agency, the Public Health Service and the Postal Service apply to the surface and air transportation of clinical laboratory specimens.

Government Regulation

General. 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. 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. OVA1 was cleared by the FDA on September 11, 2009 under the 510(k) de novo guidelines. OVA1 was the first FDA-cleared blood test for the pre-operative assessment of ovarian masses. We have not yet established a regulatory pathway for our future potential products such as VASCLIR and OVA2. Clinical studies to support either a 510(k) submission or a PMA application would need to be conducted in accordance with FDA requirements. 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. Additionally, the FDA will generally conduct a pre-approval inspection for PMA devices.

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Even in the case of devices like analyte specific reagents (ASRs), which may be exempt from 510(k) clearance or PMA approval requirements, the FDA may impose restrictions on marketing. Our potential future ASR products may be sold only to clinical laboratories certified under the CLIA to perform high complexity testing. In addition to requiring approval or clearance for new products, the FDA may require approval or clearance prior to marketing products that are modifications of existing products or the intended uses of these products. Additionally, the FDA will generally conduct a pre-approval inspection for PMA devices. Our suppliers manufacturing facilities are, and, if and when we begin commercializing and manufacturing our products ourselves, our manufacturing facilities will be, subject to periodic and unannounced inspections by the FDA and state agencies for compliance with Quality System Regulations (QSRs). Additionally, the FDA will generally conduct a pre-approval inspection for PMA devices. Although we believe that we and our suppliers will be able to operate in compliance with the FDA s QSRs for ASRs, we cannot assure that we or our suppliers will be in or be able to maintain compliance in the future. We have never been subject to an FDA inspection and cannot assure that we will pass an inspection, if and when it occurs. If the FDA believes that we or our suppliers are not in compliance with applicable laws or regulations, the FDA can issue a Form 483 List of Observations, warning letter, detain or seize our products, issue a recall notice, enjoin future violations and assess civil and criminal penalties against us. In addition, approvals or clearances could be withdrawn under certain circumstances.

Any customers using our products for clinical use in the United States may be regulated under CLIA, which is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of diagnostic tests namely, waived, moderately complex and highly complex and the standards applicable to a clinical laboratory depend on the level of the tests it performs. Medical device laws and regulations are also in effect in many of the countries in which we may do business outside the United States. These range from comprehensive device approval requirements for some or all of our potential future medical device products, to requests for product data or certifications. The number and scope of these requirements are increasing. In addition, products which have not yet been cleared or approved for domestic commercial distribution may be subject to the FDA Export Reform and Enhancement Act of 1996 (FDERA).

FDA Regulation of Cleared Tests. Once granted, a 510(k) clearance or PMA approval 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 is requiring us to perform a post-marketing study (Post-market Surveillance) to verify the performance characteristics of OVA1 in routine clinical use.

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.

Foreign Government Regulation of Our Products. We intend to obtain regulatory approval in other countries to market our tests. Each country maintains its own regulatory review process, tariff regulations, duties

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and tax requirements, product standards, and labeling requirements. In 2010, we retained the services of the Emergo Group and TUV SUD America Inc. to assist in our efforts to satisfy the regulatory requirements necessary for commercialization in Europe. In September 2010, OVA1 was CE marked, a requirement for marketing the test in the European Union.

Employees

As of December 31, 2011, we had 27 full-time employees. We also engage independent contractors from time to time.

Code of Ethics for Executive Officers

We have adopted a Code of Ethics for Executive Officers. We publicize the Code of Ethics for Executive Officers by posting the policy on our website, www.vermillion.com. We will disclose on our website any waivers of, or amendments to, our Code of Ethics.

Information About Us

We file annual reports, quarterly reports, special reports, proxy and information statements, and other information with the Securities and Exchange Commission (the SEC). You may read and copy any material we file with the SEC at the SEC s Public Reference Room located at the following address:

100 F Street, NE

Washington, DC 20549

You may obtain information on the operation of the SEC s Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

In addition, we make available free of charge under the Investors Relation section of our website, www.vermillion.com, the Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act) as soon as reasonably practicable after we have electronically filed such material with or furnished it to the SEC. The information contained on our website is not incorporated by reference in this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K. You may also obtain these documents free of charge by submitting a written request for a paper copy to the following address:

Investor Relations

Vermillion, Inc.

12117 Bee Caves Road, Building Three, Suite 100

Austin, TX 78738

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors and uncertainties together with all of the other information contained in this Annual Report on Form 10-K, including our audited consolidated financial statements and the accompanying notes in Part II Item 8, Financial Statements and Supplementary Data. 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.

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Risks Related to Our Business

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

We have experienced significant operating losses each year since our inception and we expect to incur a net loss for fiscal year 2012. 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, bankruptcy under Chapter 11 and test development.

All of our revenues are currently generated from the number of OVA1 tests sold. If we are unable to increase the volume of OVA1 sales in the near future, our consolidated results of operations and financial condition would be adversely affected.

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 as a clinical laboratory test in the US, Mexico, Britain 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 nearly all of our revenues for the foreseeable future will be derived through our strategic partnership with Quest Diagnostics and will be based on the number of OVA1 tests performed by Quest Diagnostics and the reimbursement rate received by Quest Diagnostics for those tests. 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 domestic OVA1 performed by Quest Diagnostics, as well as a 33% royalty of Quest Diagnostics gross margin from performing OVA1. 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, royalty portion of our revenue is subject to adjustment, either up or down, on an annual basis within 60 days of end of each calendar year based on Quest Diagnostics actual reimbursement history for that calendar year. To the extent Quest Diagnostics is not reimbursed, is reimbursed at a lower than expected rate, or has reimbursement claims rejected, the royalty amounts owed to us would be reduced. Any amounts owed by us to Quest Diagnostics will be deducted against payments owed to us in future periods. The number of tests performed by Quest Diagnostics and the amount of reimbursements received by Quest Diagnostics in any given period 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

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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 royalties 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 for which indications. Reimbursement rates, payment denials, appeals, and final payer determinations for OVA1 are largely out of our control, as Quest Diagnostics handles billing and reimbursement activities for all OVA1 tests performed. We are not able to predict any specific payer-level reimbursement data for OVA1 as such data is provided to us by Quest once a year as part of the annual revenue true-up process. We endeavor to maintain a dialogue with Quest Diagnostics regarding reimbursement issues as they arise. Quest Diagnostics has advised us that it has experienced volatility in the coverage and reimbursement of OVA1 due to contract negotiation with third party payers and implementation requirements and that the reimbursement amounts it has received from third party payers varies from payer to payer, and, in some cases, the variation is material. Third party payers, including private insurance companies, as well as government payers such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostic test industry. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in the reimbursement rate of payers may occur in the future. Reductions in the price at which OVA1 is reimbursed could have a material adverse effect on our revenues. If we and Quest Diagnostics 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 will 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 $20.2 million in net proceeds. However, in order to continue our operations as currently planned through 2013 and beyond, we will need to raise additional capital and thus there is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm s report on our financial statements for the year ended December 31, 2011 includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern, given our recurring net losses, negative cash flows from operations and debt outstanding due and payable in October 2012. We will 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

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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 December 31, 2011, we had $7,000,000 outstanding under our secured line of credit with Quest Diagnostics.

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 that we believe is owed to us relating to OVA1 under the terms of the Amended Strategic Alliance Agreement. The $7,000,000 secured line of credit, which is due on October 7, 2012, is secured by certain of our assets, including our patents and other intellectual property. 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. For example, markers being evaluated for OVA2 may not be validated in downstream pre-clinical or clinical studies, once we undertake and perform such studies. Although our PAD blood test in development, VASCLIR, achieved positive top-line results from an intended use clinical study, it is possible that these biomarkers, upon further analysis and clinical study, may not meet acceptance criteria for validation or regulatory clearance.

Clinical testing is expensive, takes many years to complete and can have an uncertain outcome. Clinical failure can occur at any stage of the testing. Clinical trials for our PAD, OVA2, and other future diagnostic tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing on these tests. In addition, the results of our clinical trials may identify unexpected risks relative to safety or efficacy, which could complicate, delay or halt clinical trials, or result in the denial of regulatory approval by the FDA and other regulatory authorities.

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

These factors present obstacles to 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. Additionally, Fujirebio Diagnostics, Inc. announced in September 2011 that they have received clearance from the FDA to commercialize its Risk of Malignancy Algorithm (ROMA) test, a diagnostic test that uses the biomarkers CA125 and HE4 to identify masses with a high likelihood of malignancy. The ROMA test may be in direct competition with OVA1 and our revenues could be materially and adversely affected if and when the ROMA test is successfully commercialized. In addition, competitors, such as Becton Dickinson, ArrayIt Corporation, and Abbott Labs have publicly disclosed that they have been or are currently working on ovarian cancer diagnostic assays. Academic institutions periodically report new findings in ovarian cancer diagnostics that may have commercial value. Our failure to compete with any competitive diagnostic assay if and when commercialized could adversely affect our business.

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

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

The FDA cleared OVA1 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.

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

The commercialization of our products could be delayed, halted or prevented by applicable FDA regulations. If the FDA were to view any of our actions as non-compliant, it could initiate enforcement actions, such as a warning letter and possible imposition of penalties. In addition, analyte specific reagents (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.

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.

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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. We will likely be responsible for full repayment of the secured line of credit on October 7, 2012.

As of December 31, 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. However, Quest Diagnostics has not yet acknowledged that such milestone has been achieved. We will likely 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.

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.

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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 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). In connection with the State Court lawsuit, MAS sought an unspecified amount of damages and alleged, among other things, that we breached our license agreement with MAS relating to SELDI technology by entering into a sublicense agreement with Bio-Rad. We filed our general denial and affirmative defenses on April 1, 2008. The State Court lawsuit was automatically stayed 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 in the Bankruptcy Court on July 15, 2009. The proof of claim mirrored the State Court lawsuit, alleging that we breached our license agreement with MAS 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. After the Plan of Reorganization was confirmed, MAS filed a motion with the Bankruptcy Court requesting that it abstain from hearing its proof of claim and that it grant MAS 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 16, 2010. Thereafter, the Superior Court ordered that the dispute be arbitrated before the Judicial Arbitration and Mediation Service. MAS filed its demand for arbitration on September 15, 2010. The demand did not include any additional detail regarding MAS s claims and attached the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. The parties thereafter conducted discovery, and the arbitration hearing commenced on September 21, 2011. Both sides presented evidence over five hearing days ending on October 4, 2011. The parties completed post-hearing briefing on November 9, 2011 and presented closing arguments on November 11, 2011. On February 23, 2012, an interim arbitration award was issued by the Arbitrator. In the interim arbitration award, the Arbitrator denied MAS s claim for breach of the license agreement as well as several other of MAS s claims. The Arbitrator found that MAS was entitled to an accounting concerning our 2% royalty obligation either for 10 years (from February 21, 2003 through February 21, 2013) or until cumulative royalty payments reached $10 million, whichever comes first, and ordered that such royalties should be based on our total GAAP revenues, less revenues attributable to certain excluded entities, not just SELDI-related revenues. The Arbitrator also ordered that the parties meet and confer regarding further proceedings relating to the accounting. We have accrued for the amount deemed estimable and probable of loss, and not previously paid

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to MAS, pursuant to the interim arbitration award within general and administrative expense at December 31, 2011. The amount was not material to the financial statements for the year ended December 31, 2011. We anticipate receiving a final arbitration award consistent with the interim arbitration award by June 2012 and believe the possibility of any material loss in excess of the amount accrued is remote; however, management cannot predict the content nor control the timing of the final arbitration award at this time.

On February 28, 2012, Robert Goggin III, a purported shareholder of Vermillion, filed for and obtained a writ of summons in Pennsylvania state court as a precursor to filing a lawsuit against Vermillion. Goggin discontinued his case on February 29, 2012. Thereafter, on March 12, 2012, Patrick Gillespie, a purported shareholder of Vermillion, represented by the same counsel as Goggin, filed for and obtained a writ of summons in Pennsylvania state court as a precursor to filing a lawsuit against Vermillion. On March 22, 2012, Gillespie asked the court to issue letters rogatory to permit pre-suit discovery. We dispute any claims that Gillespie may make and intend to defend this matter vigorously. Due to the fact that complaints have not yet been filed in the proceedings, we cannot estimate its likely impact on us.

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

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

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

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

Business interruptions could limit our ability to operate our business.

Our operations, as well as those of the collaborators on which we depend, are vulnerable to damage or interruption from fire; natural disasters, including earthquakes; computer viruses; human error; power shortages;

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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.

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

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

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.

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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.

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

- failure to significantly increase revenue and volumes of OVA1;
- actual or anticipated period-to-period fluctuations in financial results;
- failure to achieve, or changes in, financial estimates by securities analysts;
- announcements or introductions of new products or services or technological innovations by us or our competitors;
- publicity regarding actual or potential discoveries of biomarkers by others;
- comments or opinions by securities analysts or stockholders;
- conditions or trends in the pharmaceutical, biotechnology and life science industries;
- announcements by us of significant acquisitions and divestitures, strategic partnerships, joint ventures or capital commitments;
- developments regarding our patents or other intellectual property or that of our competitors;

litigation or threat of litigation;

additions or departures of key personnel;

limited daily trading volume;

economic and other external factors, disasters or crises; and

our announcement of additional fund raisings.

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

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

Trading of our common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market on February 15, 2012. We made the request to transfer our listing to facilitate our continued compliance with the applicable requirements for continued listing on NASDAQ. In order to maintain the listing on the Nasdaq Capital Market, we must satisfy minimum financial and other requirements, including requirements that we maintain a minimum stockholder s equity of $2.5 million and a minimum bid price of $1 per share. If we fail to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and adversely affect our ability to obtain financing for the continuation of our operations. This delisting could also impair the value of our investors investment.

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

Our certificate of incorporation, bylaws and stockholder rights plan contain provisions that could make it more difficult for a third party to acquire us, even if doing so might be deemed beneficial by our stockholders. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company. The rights issued pursuant to our stockholder rights plan will become exercisable the tenth day after a person or group announces acquisition of 15% or more of our common stock or announces commencement of a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of our common stock. If the rights become exercisable, the holders of the rights (other than the person acquiring 15% or more of our common stock) will be entitled to acquire, in exchange for the rights exercise price, shares of our common stock or shares of any company in which we are merged, with a value equal to twice the rights exercise price.

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

Certain of our stockholders or parties affiliated with 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 involvement 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 suc*h stockholders constitute a group,* as used

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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 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 $20.2 million in net proceeds. As of December 31, 2011, we had 14,900,831 shares of our common stock outstanding and 628,675 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 930,060 shares of our common stock that were subject to outstanding options. Also, as of December 31, 2011, there were 114,750 shares of restricted stock awarded to certain Executive Officers pursuant to the 2010 Plan that were not vested. These shares vest ratably through March 2014. In addition, as of December 31, 2011, warrants to purchase 195,012 shares of our common stock were outstanding at an exercise price of $9.25 per share.

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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal facility is located in Austin, Texas. The following chart indicates the facilities that we lease, the location and size of each facility and its designated use.

Location	Approximate Square Feet	Primary Functions	Lease Expiration Date
Austin, Texas	4,218 sq. ft.	Marketing, sales and administrative offices	2013
Mountain View, California	2,442 sq. ft.	Research and development, clinical and regulatory offices	2012

ITEM 3. LEGAL PROCEEDINGS

Molecular Analytical Systems, Inc. Litigation

On July 9, 2007, Molecular Analytical Systems filed a lawsuit in the Superior Court of California for the County of Santa Clara naming Vermillion and Bio-Rad as defendants (the State Court lawsuit). In connection

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with the State Court lawsuit, MAS sought an unspecified amount of damages and alleged, among other things, that we breached our license agreement with MAS relating to SELDI technology by entering into a sublicense agreement with Bio-Rad. We filed our general denial and affirmative defenses on April 1, 2008. The State Court lawsuit was automatically stayed 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 in the Bankruptcy Court on July 15, 2009. The proof of claim mirrored the State Court lawsuit, alleging that we breached our license agreement with MAS 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. After the Plan of Reorganization was confirmed, MAS filed a motion with the Bankruptcy Court requesting that it abstain from hearing its proof of claim and that it grant MAS 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 16, 2010. Thereafter, the Superior Court ordered that the dispute be arbitrated before the Judicial Arbitration and Mediation Service. MAS filed its demand for arbitration on September 15, 2010. The demand did not include any additional detail regarding MAS s claims and attached the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. The parties thereafter conducted discovery, and the arbitration hearing commenced on September 21, 2011. Both sides presented evidence over five hearing days ending on October 4, 2011. The parties completed post-hearing briefing on November 9, 2011 and presented closing arguments on November 11, 2011. On February 23, 2012, an interim arbitration award was issued by the Arbitrator. In the interim arbitration award, the Arbitrator denied MAS s claim for breach of the license agreement as well as several other of MAS s claims. The Arbitrator found that MAS was entitled to an accounting concerning our 2% royalty obligation either for 10 years (from February 21, 2003 through February 21, 2013) or until cumulative royalty payments reached $10 million, whichever comes first, and ordered that such royalties should be based on our total GAAP revenues, less revenues attributable to certain excluded entities, not just SELDI-related revenues. The Arbitrator also ordered that the parties meet and confer regarding further proceedings relating to the accounting. We have accrued for the amount deemed estimable and probable of loss, and not previously paid to MAS, pursuant to the interim arbitration award within general and administrative expense at December 31, 2011. The amount was not material to the financial statements for the year ended December 31, 2011. We anticipate receiving a final arbitration award consistent with the interim arbitration award by June 2012 and believe the possibility of any material loss in excess of the amount accrued is remote; however, management cannot predict the content nor control the timing of the final arbitration award 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 our 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 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

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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 within general and administrative expense at December 31, 2011 and 2010. Management cannot predict the ultimate outcome of this matter at this time.

Patrick Gillespie Litigation

On February 28, 2012, Robert Goggin III, a purported shareholder of Vermillion, filed for and obtained a writ of summons in Pennsylvania state court as a precursor to filing a lawsuit against Vermillion. Goggin discontinued his case on February 29, 2012. Thereafter, on March 12, 2012, Patrick Gillespie, a purported shareholder of Vermillion, represented by the same counsel as Goggin, filed for and obtained a writ of summons in Pennsylvania state court as a precursor to filing a lawsuit against Vermillion. On March 22, 2012, Gillespie asked the court to issue letters rogatory to permit pre-suit discovery. We dispute any claims that Gillespie may make and intend to defend this matter vigorously. Due to the fact that complaints have not yet been filed in the proceedings, we cannot estimate its likely impact on us.

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 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock was traded on the Nasdaq Global Market under the symbol VRML. Effective February 15, 2012, we transferred our listing from the NASDAQ Global Market to the NASDAQ Capital Market.

On September 25, 2008, our common stock was delisted from and suspended from trading on The Nasdaq Capital Market as a result of our noncompliance with the listing criteria under Marketplace Rule 4310(c)(3). Upon delisting from The Nasdaq Capital Market, our common stock became immediately eligible for quotation and began trading over-the-counter (OTC) on Pink Quote, formerly known as Pink Sheets, electronic quotation system (Pink Quote) on September 25, 2008, under the ticker symbol VRML.PK . After a market maker s application to trade our common stock on the OTC Bulletin Board was approved by the Financial Industry Regulatory Authority, our common stock began trading on the OTC Bulletin Board under the ticker symbol VRML.OB on October 10, 2008.

In connection to our March 30, 2009 filing for relief under the Bankruptcy Code in the Bankruptcy Court, our common stock began trading under the ticker symbol VRMLQ.OB on April 6, 2009. On April 20, 2009, our common stock began trading under the ticker symbol VRMQE.OB as a result of us becoming a delinquent filer of our required financial reports to the SEC under the National Association of Securities Dealers, Inc. (NASD) Rule 6530. After a 30-day grace period on May 20, 2009, our common stock was delisted from the OTC Bulletin Board for noncompliance with NASD Rule 6530. Upon delisting from the OTC Bulletin Board, our common stock became immediately eligible for quotation and began trading on Pink Quote under the ticker symbol VRMLQ.PK on May 20, 2009. On January 27, 2010, our common stock began trading under the symbol VRML.PK in connection with our emergence from bankruptcy under the Bankruptcy Code on January 22, 2010.

On July 6, 2010, The Nasdaq Stock Market LLC relisted our common stock on The Nasdaq Global Market. On March 8, 2012, there were 72 registered holders of record of our common stock, including multiple beneficial holders and depositories, banks and brokers listed as a single holder in the street name of each respective depository, bank or broker. The closing price of our common stock on March 19, 2012 was $1.61.

The following sets forth the quarterly high and low trading prices as reported by The Nasdaq Global Market and Pink Quote for the periods indicated.

	2011		2010	
	High	Low	High	Low
First Quarter	$ 9.25	$ 3.75	$ 34.00	$ 20.90
Second Quarter	7.60	3.33	29.00	10.95
Third Quarter	4.36	2.14	13.50	4.95
Fourth Quarter	2.89	0.97	9.49	4.53

Dividends

We have never paid or declared any dividend on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future. If we pay a cash dividend on our common stock, we also may be required to pay the same dividend on an as-converted basis on any outstanding preferred stock, warrants, convertible notes or other securities. Moreover, any preferred stock or other senior debt or equity securities to be issued and any future credit facilities might contain restrictions on our ability to declare and pay dividends on our common stock. We intend to retain all available funds and any future earnings to fund the development and expansion of our business.

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Unregistered Sales of Equity Securities

On January 7, 2010, we closed a private placement transaction with a group of investors. We received $43,050,000 in gross proceeds from the sale of 2,327,869 shares of our common stock at a price of $18.4932 per share. The shares of our common stock issued in connection with the private placement were exempted from the registration requirement pursuant to Regulation D of the Securities Act. Accordingly, these restricted shares were subject to the resale limitations of Rule 144 under the Securities Act, as a transaction not involving a public offering because, among other things, the investors were accredited investors at the time of the transaction and appropriate legends were affixed to the instruments representing such securities issued in such transaction.

From November 30, 2009, through January 22, 2010, we exchanged 428,906 shares of our common stock for $7,100,000 in principal and unpaid interest of $732,000 related to the convertible senior notes due September 1, 2011. From October 21, 2009 through November 19, 2009, $4,400,000 in principal related to the 7.00% Notes was converted into 220,000 shares of our common stock. The offer and issuance of the securities was exempt from registration under Section 3(a)(9) of the Securities Act.

From November 24, 2009 to January 22, 2010, we exchanged a total of 15,794 shares of our common stock for $305,000 in principal and $18,000 in unpaid interest related to the convertible senior notes due September 1, 2009 (the 4.50% Notes). The offer and issuance of the securities was exempt from registration under Section 3(a)(9) of the Securities Act.

From October 5, 2009, through April 12, 2010, we issued 990 shares of our common stock for $12,000 from the cash exercise of warrants dated August 3, 2006, with an exercise price of $12.60 per share (the August 3 Warrants), and 3,496 shares of our common stock from the cashless exercise of 8,625 underlying common stock shares of the August 3 Warrants. From October 5, 2009, through April 12, 2010, we issued 990 shares of our common stock for $12,000 from the cash exercise of warrants dated November 15, 2006, with an exercise price of $12.60 per share (the November 15 Warrants), and 3,486 shares of our common stock from the cashless exercise of 8,625 underlying common stock shares of the November 15 Warrants. From September 29, 2009, through March 4, 2010, we issued 392,120 shares of our common stock for $3,627,000 from the cash exercise of warrants dated August 29, 2007, with an exercise price of $9.25 per share (the 2007 Warrants), and 521,213 shares of our common stock from the cashless exercise of 1,435,678 underlying common stock shares of the 2007 Warrants. The offer and issuance of securities is subject to the resale limitations of Rule 144 under the Securities Act.

Equity Compensation Plan Information

We currently maintain three equity-based compensation plans that were approved by our stockholders. The plans are the Amended and Restated 2000 Stock Plan (the 2000 Plan), the Amended and Restated 2000 Employee Stock Purchase Plan (the 2000 ESPP), and the 2010 Stock Incentive Plan (the 2010 Plan).

2000 Plan. The authority of our Board of Directors to grant new stock options and awards under the 2000 Plan terminated in 2010. The Board of Directors continues to administer the 2000 Plan with respect to the stock options that remain outstanding to our officers, employees, directors and a consultant. At December 31, 2011, options to purchase 596,047 shares of common stock remained outstanding under the 2000 Plan.

2010 Plan. The 2010 Plan is administered by the Compensation Committee of the Board. Our 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, and unrestricted shares, deferred share units, performance and cash-settled awards, and dividend equivalent rights. We are authorized to issue 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. At December 31, 2011, options to purchase 334,013 shares of common stock remained outstanding under the 2010 Plan.

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The number of shares of our common stock to be issued upon exercise of outstanding stock options, the weighted-average exercise price of outstanding stock options and the number of shares available for future stock option grants and stock awards under equity compensation plans as of December 31, 2011, were as follows:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Shares Reflected in First Column)
Equity compensation plans approved by security holders	930,060[1]	$ 12.97[2]	628,675[3]
Equity compensation plans not approved by security holders			
Total	930,060		628,675

(1) Includes outstanding stock options for 596,047 shares of our common stock under the 2000 Plan and 334,013 shares of our common stock under the 2010 Plan.
(2) Includes the weighted average stock price for outstanding stock options of $14.01 under the 2000 Plan and $11.11 for the 2010 Plan.
(3) Includes 628,675 shares of our common stock for the 2010 Plan. No future awards shall occur under the 2000 Plan.

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Performance Graph

Pursuant to Instructions to Item 201(e)(6) of Regulation S-K, information is not required.

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ITEM 6. SELECTED FINANCIAL DATA

Per Item 301(c) of Regulation S-K, information is not required.

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis in conjunction with our Consolidated Financial Statements and related Notes thereto, included on pages F-1 through F-31 of this Annual Report on Form 10-K, and Risk Factors , which are discussed in Item 1A. The statements below contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act. See Forward-Looking Statements on page i.

Overview

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

We are dedicated to the discovery, development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Our tests are intended to 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. Management (we , us or our) concentrate its development of novel diagnostic tests in the fields of oncology, cardiology and women s health, with our 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.

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 Bankruptcy case was formally closed on January 19, 2012.

Our lead product, OVA1, was cleared by the FDA on September 11, 2009. OVA1 addresses a clear unmet clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary FDA-cleared software to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 was developed through large 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 in a clinical cohort of 516 patients, OVA1, in conjunction with clinical evaluation, was able to identify 95.6% (154/161) of the malignant ovarian tumors overall, and to rule out malignancy with a negative predictive value (NPV) of 94.6% (123/130). Recently, 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 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.

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OVA1 is currently being offered by Quest Diagnostics. 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, 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 consists of the US, Mexico, Britain and India, through September 11, 2014. Quest has the right to extend the exclusivity period for one additional year on the same terms and conditions. OVA1 was CE marked in September 2010, a requirement for marketing the test in the European Union. Quest Diagnostics has the right to extend the exclusivity period for an additional year beyond September 11, 2014 on the same terms and conditions. An estimated 21,380 OVA1s have been performed from the launch on March 9, 2010 through December 31, 2011.

In addition to OVA1, we have development programs in other clinical aspects of ovarian cancer as well as in peripheral arterial disease, or PAD. In the field of peripheral arterial disease, we have identified candidate biomarkers that may help to identify individuals at high risk for a decreased ankle-brachial index score, which is indicative of the likely presence of PAD. We have recently completed an intended-use study to develop and validate a multi-marker algorithm for the assessment of individuals at risk for peripheral arterial disease. This algorithm will be specifically directed at a primary care population in which the peripheral arterial disease blood test (VASCLIR) is expected to be used. Once this study has been published in the peer-reviewed literature, we intend to discuss with the FDA the appropriate submission pathway, which may be PMA, 510(k) clearance, or 510(k) de novo clearance. Vasclir is subject to the Quest Diagnostics Strategic Alliance.

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 January 11, 2011, we were issued patent number 7,867,719 entitled Beta-2 microglobulin as a biomarker for peripheral artery disease by the USPTO. The patent claims are directed to beta-2 microglobulin and biomarker combinations that include beta-2 microglobulin for the diagnosis and management of peripheral artery disease and to the measurement of the biomarkers by a variety of methods, including mass spectrometry and immunoassay.

On February 2, 2011, we announced that the USPTO has issued to us a notice of allowance for a patent entitled Biomarkers for breast cancer . The patent claims are directed to biomarker combinations for the diagnosis and management of breast cancer and to the measurement of the biomarkers by mass spectrometry.

On February 3, 2011, we received payment for an award of two grants, approved in November 2010, for the aggregate sum of $489,000 under the Internal Revenue Service Qualifying Therapeutic Discovery Projects Grant Program for our OVA2 and PAD programs. The grant relates to 2010 expenditures and was awarded to therapeutic or diagnostic discovery projects that show a reasonable potential to result in new therapies or diagnostic tests that address areas of unmet medical need or that prevent, detect or treat chronic or acute diseases and conditions. These grants were included in other income for the year ended December 31, 2010 and were recorded as other current assets at December 31, 2010.

On February 18, 2011, we completed a sale of 4,000,000 shares of our common stock in an underwritten 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.

On March 8, 2011, positive preliminary data from our collaboration with Johns Hopkins University School of Medicine to identify biomarkers that improve on the specificity of CA125 for the identification of malignant ovarian tumors were presented at the 42nd Annual Meeting on Women s Cancer of the Society of Gynecologic Oncologists, March 6-9, 2011 in Orlando, Florida.

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On March 14, 2011, we announced the inclusion of OVA1 as part of the recently published ACOG/SGO committee opinion. In the March edition of Obstetrics and Gynecology, the American College of Obstetricians and Gynecologists (ACOG) and Society of Gynecologic Oncologists (SGO) published an update committee opinion on the role of the obstetrician-gynecologist in the early detection of epithelial ovarian cancer. This updates the original opinion, which was published in 2002.

On April 4, 2011, we announced the signing of an agreement with Quest Diagnostics to make OVA1 available in India. Additionally, at the International Gynecologic Cancer Society (IGCS) regional meeting held in New Delhi from April 2-3, 2011, Dr. Fred Ueland, M.D., Associate Professor of Gynecologic Oncology at the University of Kentucky s Markey Cancer Center presented data demonstrating the high sensitivity for ovarian malignancy of OVA1 combined with ultrasound.

On May 17, 2011, we announced that the 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.

In the June 2011 edition of Obstetrics & Gynecology, two landmark papers were published on the clinical validation of OVA1, supporting FDA clearance. The first, by Ueland et al., showed that OVA1correctly identified 70% and 95% of malignancies missed by non-gynecologic oncologists and gynecologic oncologists, respectively. Physician assessment plus the OVA1 also detected 86% of malignancies missed by CA125, a biomarker commonly used off label in the screening and diagnosis of ovarian cancer. The second, by Ware Miller et al., demonstrated that replacement of CA125 by OVA1 in the American College of Obstetricians and Gynecologists (ACOG) guidelines for referral of a pelvic mass improves the sensitivity and negative predictive value of the guidelines. The high sensitivity is maintained even in premenopausal women and early-stage disease, two particularly challenging diagnostic groups.

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 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.

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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.

On September 6, 2011, we announced that the USPTO has issued patent number 8,014,952 entitled Serum Biomarkers in Lung Cancer to the Company.

On September 14, 2011, we announced the presentation of data by Fred Ueland, M.D., Associate Professor of Gynecologic Oncology at the University of Kentucky s Markey Cancer Center, and principal investigator of the multi-center OVA1 clinical trial, demonstrating the improvement in sensitivity when using imaging in conjunction with OVA1. The key finding from Dr. Ueland s presentation at the 17th Annual European Society of Gynecologic Oncology meeting held in Milan from September 11th to 14th, 2011 is that OVA1, when combined with imaging, achieved 98.1% sensitivity for all types of ovarian cancers and obtained a negative predictive value of 96.3%. A higher OVA1 score also correlated with an increasing risk of ovarian malignancy.

On September 29, 2011, our Board of Directors determined that it was appropriate for the Company to separate the role of Chairman of the Board from the role of Chief Executive Officer. To this end, Gail S. Page resigned her role as Chairman of the Board and the Board elected James S. Burns as Chairman of the Board. Mr. Burns has been a director of the Board since 2005. Ms. Page will continue in her role as President and Chief Executive Officer of the Company and as a member of the Board.

On September 26, 2011, we announced the appointment of Donald Munroe, Ph.D. as Chief Scientific Officer and Vice President of Research and Development. In conjunction with Dr. Munroe s hiring, Eric T. Fung, MD, Ph.D. became Chief Medical Officer. These changes were effective as of October 11, 2011.

On October 3, 2011, we announced positive top-line results from the intended use study of our PAD blood test, VASCLIR. The goals of the study were to validate the markers described in earlier publications (*Circulation*, 2007 and *Vascular Medicine*, 2008) and to develop and validate a biomarker panel applicable to the intended use population.

Key results of the study include the following:

- The individual biomarkers beta-2 microglobulin (B2M), cystatin C, and hsCRP (high sensitivity c-reactive protein), each has statistically significant different levels between PAD subjects and non-PAD subjects ($p<.001$).
- Each biomarkers showed statistically significant correlation to the ankle-brachial index or ABI ($p<.001$).
- A logistic regression model was able to identify more than 80% of PAD patients among those deemed low-risk by the conventional Framingham Risk Score for estimating cardiovascular disease probability.

The intended use study was a prospective, double-blinded multi-center study of approximately 1,000 subjects who met specific inclusion criteria for being at increased risk of having PAD, including smokers and diabetics age 50 or above and elderly age 70 or above. The study was conducted in conjunction with CPC Clinical Research, led by William R. Hiatt, MD, who is currently the Novartis Foundation endowed professor for cardiovascular research in the Department of Medicine, University of Colorado School of Medicine appointed in cardiology and a clinical focus in vascular medicine.

On October 5, 2011, Sandra A. Gardiner announced her resignation as our Vice President and Chief Financial Officer, effective October 21, 2011. Ms. Gardiner accepted an employment opportunity in the San Francisco Bay Area and her resignation was not the result of any disagreement with the Company on any matter relating to the Company s operations, policies or practices. In conjunction with Ms. Gardiner s resignation, Eric Schoen was appointed as our Chief Accounting Officer effective October 6, 2011.

On November 2, 2011, the Company entered into a consulting agreement with Eric T. Fung, MD, Ph.D., effective on November 4, 2011. Pursuant to the terms of the consulting agreement, Dr. Fung will continue to serve as the Company s Chief Medical Officer and a member of the Company s Scientific Advisory Board.

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On November 3, 2011, we announced the receipt of a notice of allowance from the USPTO for our fifth patent covering a combination of biomarkers that could be used in the diagnosis of PAD. The patent, entitled Beta-2 Microglobulin (B2M) and C Reactive Protein (CRP) as Biomarkers for Peripheral Artery Disease, involves a unique combination of B2M and CRP, two proteins that have been demonstrated in numerous studies to be associated with PAD.

On December 19, 2011, we announced the completion of an asset purchase agreement with Correlogic, pursuant to which, subject to the satisfaction of certain conditions, we agreed to pay to Correlogic $435,000 and purchase from Correlogic substantially all of its assets, including, without limitation, certain documents, diagnostic samples and intellectual property owned by and licensed to Correlogic in connection with Correlogic s ovarian cancer diagnostics business, including a diagnostic test under the name OvaCheck2 for the detection of ovarian cancer. The assets were acquired under Sections 105 and 363 of the Chapter 11 of the U.S. Bankruptcy Code.

On February 9, 2012, we entered into a Settlement Agreement and Release (the Settlement Agreement) with a third party related to losses on our short and long-term investments in previous years. Under the terms of the Settlement Agreement, we will receive a total settlement of $1,000,000 (the Total Settlement Amount); $535,000 was paid in March 2012 and $465,000 is payable by September 1, 2012. We expect to receive approximately 70% of the Total Settlement Amount, net of legal and related costs.

On March 5, 2012 we announced the receipt of a notice of allowance from the USPTO for Platelet biomarkers for cancer. The patent resulted from a collaboration with the late Dr. Judah Folkman, a renowned cancer expert, and identifies three biomarkers that can be used to assess changes in endogenous angiogenesis in a subject. Angiogenesis is commonly associated with cancer, and novel therapeutics such as bevacizumab (Avastin®) target angiogenesis to limit tumor recruitment of blood vessels. The patented biomarkers, which are associated with platelets, can be used to measure ongoing angiogenic activity. The patent covers the measurement of these biomarkers over time and correlating changes in expression with the changing level of endogenous angiogenic activity. Consequently, this patent also enables the use of these biomarkers to monitor efficacy of therapy directed at angiogenic pathways.

On March 6, 2012, the American Medical Association (AMA) Current Procedural Terminology (CPT®) Panel voted to approve an application for a Category I CPT code for OVA1. The AMA recently disclosed the new code on its website, which will become effective January 1, 2013.

Critical Accounting Policies and Estimates

The notes to the consolidated financial statements contain a summary of the Company s significant accounting policies that are presented in Part II Item 8, Financial Statements and Supplementary Data , of this Annual Report on Form 10-K. We believe that it is important to have an understanding of certain policies, along with the related estimates that we are required to make in recording the financial transactions of the Company, in order to have a complete picture of the Company s financial condition. In addition, in arriving at these estimates, we are required to make complex and subjective judgments, many of which include a high degree of uncertainty. The following is a discussion of these critical accounting policies and significant estimates related to these policies.

Revenue Recognition

Product Revenue. We derive our product revenues from sales of OVA1 through Quest Diagnostics. We recognize product revenues for tests performed when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

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License Revenue. Under the terms of the secured line of credit with Quest Diagnostics, portions of the borrowed principal amounts may be forgiven upon our achievement of certain milestones relating to the development, regulatory approval and commercialization of certain diagnostic tests. We account for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest Diagnostics receives upon commercialization of an approved diagnostic test as we do not have a meaningful history of product sales that provides a reasonable basis for estimating future product sales. We recognize license revenue on a straight-line basis over the remaining period of Quest Diagnostics sales exclusivity ending in September 2015.

Fair Value of Warrants

We classify certain of our outstanding warrants as liabilities on our balance sheet. In addition, we fair value these stock warrants at each reporting period, with the changes in fair value recognized in our consolidated statements of operations. We fair value the warrants using a Black Scholes valuation model. Since the outstanding common stock warrants are fair valued at the end of each reporting period, any change in the underlying assumptions to the Black Scholes valuation model, including the volatility and price of our common stock, may have a significant impact on our consolidated financial statements.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist primarily of payroll and related costs, materials and supplies used in the development of new products, and fees paid to third parties that conduct certain research and development activities on behalf of the Company. In addition, acquisitions of assets to be consumed in research and development, with no alternative future use, are expensed as incurred as research and development costs. Software development costs incurred in the research and development of new products are expensed as incurred until technological feasibility is established.

Stock-Based Compensation

We record the fair value of non-cash stock-based compensation costs for stock options and stock purchase rights related to our 2010 Stock Incentive Plan (the 2010 Plan) and 2000 Stock Plan (the 2000 Plan). We estimate the fair value of stock options using a Black-Scholes option valuation model. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. We use the straight-line method to amortize the fair value over the vesting period of the award. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, option exercise patterns and forfeitures, the actual value of stock options and stock purchase rights could differ from our estimates.

We also record the fair value of non-cash stock-based compensation costs for equity instruments issued to non-employees. We recalculate costs for these options each reporting period using a Black-Scholes option valuation model. Because we recalculate these costs each reporting period, changes in assumptions used in our calculations, including changes in the fair value of our common stock, can result in significant changes in the amounts we record from one reporting period to another.

Contingencies

We account for contingencies in accordance with ASC 450 Contingencies (ASC 450). ASC 450 requires that an estimated loss from a loss contingency shall be accrued when information available prior to issuance of the financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and when the amount of the loss can be reasonably estimated. Accounting for contingencies such as legal and contract dispute matters requires us to use our judgment. We believe that our accruals for these matters are adequate. Nevertheless, the actual loss from a loss contingency might differ from our estimates.

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Income Taxes

Our income tax policy records the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying balance sheets, as well as operating loss and tax credit carry forwards. We have recorded a full valuation allowance to reduce our deferred tax assets, as based on available objective evidence; it is more likely than not that the deferred tax assets will not be realized. In the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax assets would increase net income in the period such determination was made.

Recently Adopted Accounting Pronouncements

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, results of operations or cash flows but it will impact the way we present comprehensive income.

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.

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Results of Operations Year Ended December 31, 2011 as compared to Year Ended December 31, 2010

The selected summary financial and operating data of Vermillion for the years ended December 31, 2011 and 2010 were as follows:

(dollars in thousands)	Year Ended December 31, 2011	2010	Increase (Decrease) Amount	%
Revenue:				
Product	$ 1,469	$ 308	$ 1,161	377
License	454	867	(413)	(48)
Total revenue	1,923	1,175	748	64
Cost of revenue:				
Product	129	88	41	47
Total cost of revenue	129	88	41	47
Gross profit	1,794	1,087	707	65
Operating expenses:				
Research and development	5,387	3,848	1,539	40
Sales and marketing	5,539	2,857	2,682	94
General and administrative	8,509	8,984	(475)	(5)
Total operating expenses	19,435	15,689	3,746	24
Loss from operations	(17,641)	(14,602)	(3,039)	21
Interest income	64	40	24	60
Interest expense	(396)	(491)	95	(19)
Gain on investments in auction rate securities	-	58	(58)	-
Change in fair value and gain from warrant exercise, net	378	4,353	(3,975)	(91)
Debt conversion costs	-	(141)	141	-
Reorganization items	(96)	(1,677)	1,581	(94)
Reorganization items related party incentive plan	-	(6,932)	6,932	-
Other income (expense), net	(99)	358	(457)	(128)
Loss before income taxes	(17,790)	(19,034)	1,244	(7)
Income tax benefit (expense)	-	-	-	-
Net loss	$ (17,790)	$ (19,034)	$ 1,244	(7)

Product Revenue. Product revenue was $1,469,000 for the year ended December 31, 2011 compared to $308,000 for the same period in 2010. We recognized product revenue for the year ended December 31, 2011 for the sale of OVA1 through Quest Diagnostics. Quest Diagnostics performed approximately 15,225 OVA1 tests during the year ended December 31, 2011 compared to approximately 6,155 tests for the same period in 2010. We commercially launched OVA1 on March 9, 2010. Product revenue increased $1,161,000 for the year ended December 31, 2011 compared to the same period in 2010 due to the increased volume of tests as well as the recognition of deferred revenue upon meeting the criteria for revenue recognition. During the fourth quarter of 2011, we recognized $549,000 of deferred revenue related to 2011 upon receipt of an annual royalty report from Quest Diagnostics based on final resolution for 11,708 tests. During the first quarter of 2011, we recognized $160,000 of deferred revenue related to 2010 upon receipt of an annual royalty report from Quest Diagnostics based on final resolution for 2,814 tests. Tests which do not yet have final resolution for 2011 will be included in our 2012 annual royalty report. During 2010, we recognized only the $50 fixed fee per test in product revenue and recorded additional payments as deferred revenue.

License Revenue. License revenue was $454,000 for the year ended December 31, 2011 compared to $867,000 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 approval for OVA1. This amount is recognized

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as license revenue over the period of sales exclusivity Quest Diagnostics received beginning on the OVA1 commercialization date of March 9, 2010. License revenue decreased $413,000, or 48%, for the year ended December 31, 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.

Cost of Product Revenue. 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 revenue was $129,000 for the year ended December 31, 2011 compared to $88,000 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 $1,539,000, or 40%, for the year ended December 31, 2011 compared to the same period in 2010. This increase was due primarily to a $1,919,000 increase in clinical trial and collaboration costs for the ongoing development of our ovarian cancer program and our PAD blood test, VASCLIR, as well as $435,000 for the Correlogic asset acquisition which was expensed as the assets acquired will be consumed in research and development activities, with no alternative future use. These increases were partially offset by decreases in stock-based compensation expense of $307,000 as well as decreases in depreciation expense and outside consulting services compared to the same period in 2010 as well as a loss on sale and disposal of property and equipment in 2010 which did not recur in 2011. We expect research and development expenses to be lower in 2012 as compared to 2011 as we completed our PAD intended-use study in 2011 and anticipated 2012 activities will be less cost intensive. Our research and development expenses may fluctuate from period to period due to the timing and scope of our activities as well as coordination of our activities with current and potential collaborators and strategic partners.

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 Diagnostic s sales team. Sales and marketing expenses increased by $2,682,000, or 94%, for the year ended December 31, 2011 compared to the same period in 2010. The increase was primarily due to a $1,844,000 increase in personnel and personnel-related expenses, reflecting a full year with the sales and marketing team while the Territory Development Managers were added over the course of 2010, a $540,000 increase in marketing expenses related to the continued commercialization and promotion of OVA1 as well as $141,000 increase in outside consulting services. We expect sales and marketing expenses to be lower in 2012 as compared to 2011 as a result of our reduction in our Territory Development and sales management personnel announced in January 2012. Our sales and marketing expenses may fluctuate from period to period due to the timing and scope of our activities as well as coordination of our activities with current and potential collaborators and strategic partners.

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 decreased by $475,000, or 5%, for the year ended December 31, 2011 compared to the

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same period in 2010. The decrease was primarily due to a $1,422,000 decrease in stock compensation expense as Incentive Plan costs were fully amortized in June 2011. In addition, audit and tax related service costs decreased $781,000 compared to the same period in 2010 due to the substantial effort in 2010 to bring current all periodic reports required by the Securities and Exchange Act of 1934 following emergence from bankruptcy. These decreases were partially offset by a $1,662,000 increase in legal costs due to the MAS litigation as well as Correlogic and shareholder activist litigation legal costs. General and administrative stock-based compensation expense was $2,446,000 and $3,868,000 for the years ended December 31, 2011 and 2010, respectively. We expect general and administrative expenses to be lower in 2012 as compared to 2011 as a result of our eliminating the positions of Chief Financial Officer and Vice President of Corporate Strategy as announced in January 2012. We also anticipate a reduction in our legal expenses in 2012 compared to 2011 as significant legal matters, including the MAS litigation, are expected to come to closure during 2012. Our general and administrative expenses may fluctuate from period to period due to the timing and scope of our activities as well as coordination of our activities with current and potential collaborators and strategic partners.

Interest Expense. Interest expense decreased by $95,000, or 19%, for the year ended December 31, 2011 compared to the same period in 2010 as we paid off $5,000,000 of our 7.00% Senior Convertible Notes upon maturity in September 2011.

Gain on Investment in Auction Rate Securities. There was no gain on investment in auction rate securities for the year ended December 31, 2011 compared to $58,000 in the same period in 2010. The auction rate securities were sold in July 2010.

Change in Fair Value and Gain from Warrant Exercise, Net. The change in fair value and gain from exercise of warrants was $378,000 for the year ended December 31, 2011 compared to $4,353,000 for the same period in 2010. The decrease of $3,975,000, or 91%, was primarily due to the relative decrease in the Company s stock price during the respective annual periods.

Debt Conversion Costs. There were no debt conversion costs for the year ended December 31, 2011 compared to $141,000 for the same period in 2010 as there was no conversion of debt to equity in 2011.

Reorganization Items. Reorganization items for the year ended December 31, 2011 totaled $96,000 compared to $1,677,000 for the same period in 2010. Reorganization items include professional advisory fees and other costs directly associated with our Chapter 11 bankruptcy activities. The activities were largely completed during 2010 resulting in lower expenses during the year ended December 31, 2011. We expect costs related to reorganization items to be immaterial in 2012.

Reorganization Items Related Party Incentive Plan. All Incentive Plan expenses during 2011 were included in general and administrative expense. Reorganization items for the year ended December 31, 2010 amounted to $6,932,000. We paid $5,000,000 in cash and accrued $1,932,000 for the value of the vested portions of restricted stock under the Incentive Plan prior to us emerging from bankruptcy under the Bankruptcy Code.

Other Income (Expense), Net. Net other expense was $99,000 for the year ended December 31, 2011 compared to other income of $358,000 for the same period in 2010. Other expense for 2011 was due primarily to Delaware franchise tax. Other income for the year ended December 31, 2010 included an award of two grants for the aggregate sum of $489,000 under the Internal Revenue Service Qualifying Therapeutic Discovery Projects Grant Program for the OVA2 and PAD programs.

Income Tax Benefit (Expense). There was no income tax benefit or expense for the year ended December 31, 2011 or 2010.

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Results of Operations Year Ended December 31, 2010 as compared to Year Ended December 31, 2009

The selected summary financial and operating data of Vermillion for the years ended December 31, 2010 and 2009 were as follows:

(dollars in thousands)	Year Ended December 31, 2010	2009	Increase (Decrease) Amount	%
Revenue:				
Product	$ 308	$	$ 308	
License	867		867	
Total revenue	1,175		1,175	
Cost of revenue:				
Product	88		88	
Total cost of revenue	88		88	
Gross profit	1,087		1,087	
Operating expenses:				
Research and development	3,848	2,346	1,502	64
Sales and marketing	2,857	455	2,402	528
General and administrative	8,984	2,562	6,422	251
Total operating expenses	15,689	5,363	10,326	193
Loss from operations	(14,602)	(5,363)	(9,239)	172
Interest income	40	28	12	43
Interest expense	(491)	(1,691)	1,200	(71)
Gain on investments in auction rate securities	58		58	
Change in fair value and gain from warrant exercise, net	4,353	(12,106)	16,459	(136)
Debt conversion costs	(141)	(819)	678	(83)
Reorganization items	(1,677)	(2,066)	389	(19)
Reorganization items related party incentive plan	(6,932)		(6,932)	
Other income (expense), net	358	(20)	378	(1,890)
Loss before income taxes	(19,034)	(22,037)	3,003	(14)
Income tax benefit (expense)		(11)	11	
Net loss	$ (19,034)	$ (22,048)	$ 3,014	(14)

Product Revenue. Product revenue was $308,000 for the year ended December 31, 2010. We recognized product revenue for the year ended December 31, 2010 for sales of OVA1 through Quest Diagnostics. OVA1 was launched on March 9, 2010 and thus there was no product revenue for the year ended December 31, 2009.

License Revenue. License revenue was $867,000 for the year ended December 31, 2010. Under the terms of our secured line of credit with Quest Diagnostics, $3,000,000 principal was forgiven upon the achievement of FDA approval for OVA1. This amount is recognized as license revenue over the period of sales exclusivity Quest Diagnostics received beginning on the OVA1 commercialization date of March 9, 2010. Thus, there was no license revenue for the year ended December 31, 2009.

Cost of Product Revenue. 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 $88,000 for the year ended December 31, 2010. There was no cost of product revenue for the year ended December 31, 2009.

Research and Development Expenses. Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs,

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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 $1,502,000, or 64%, for the year ended December 31, 2010 compared to the same period in 2009. This increase included a $774,000 increase in stock-based compensation, a $454,000 increase in personnel-related expenses due to the increased headcount after the emergence from bankruptcy under the Bankruptcy Code, and a $137,000 increase in collaboration and clinical trial costs due to our development in other clinical aspects of ovarian cancer as well as our intended-use study for PAD. These items were partially offset by a $206,000 decrease in depreciation expense. Stock-based compensation expense increased to $992,000 for the year ended December 31, 2010 compared to $219,000 for the same period in 2009.

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. Sales and marketing expenses increased by $2,402,000, or 528%, for the year ended December 31, 2010 compared to the same period in 2009. The increase was primarily due to a $1,492,000 increase in personnel and personnel-related expenses, reflecting the addition of fifteen sales and marketing employees in the year ended December 31, 2010, and a $540,000 increase in marketing expenses related to the commercialization and launch of 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 $6,422,000, or 251%, for the year ended December 31, 2010 compared to the same period in 2009. The increase was primarily due to a $1,967,000 increase in legal, audit and tax related services and a $573,000 increase in personnel-related expenses. Personnel, consulting, legal, audit and tax related expenses increased due to significant efforts to bring current all periodic reports required by the Exchange Act upon our emergence from bankruptcy. Stock-based compensation expense was $831,000 and $328,000 for the years ended December 31, 2010 and 2009, respectively. Under the terms of the Debtor s Incentive Plan, we also incurred $3,037,000 as related party incentive expenses during the year ended December 31, 2010 for the value of the vested portions of restricted stock issued.

Interest Income. Interest income increased by $12,000, or 43%, for the year ended December 31, 2010, compared to the same period in 2009.

Interest Expense. Interest expense decreased by $1,200,000, or 71%, for the year ended December 31, 2010, compared to the same period in 2009. Interest expense in both periods consisted largely of interest related to our convertible senior notes and long-term debt; however, total debt outstanding at December 31, 2010 was $12,000,000 compared to $17,765,000 at December 31, 2009 and our rate of interest was reduced in 2010 compared to 2009.

Gain on Investment in Auction Rate Securities. Gain on investment in auction rate securities totaled $58,000 for the year ended December 31, 2010 compared to none in the same period for 2009. The auction rate securities were sold in July 2010, eliminating our position in the investment.

Change in Fair Value and Gain from Warrant Exercise, Net. The change in fair value and gain from exercise of warrants of $4,353,000 for the year ended December 31, 2010 was primarily due to the change in our stock price during the year then ended. Effective January 1, 2009, the adoption of the new accounting guidance resulted in the reclassification of certain outstanding common stock warrants from stockholders deficit to liability, which further required re-measurement at the end of each reporting period.

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Debt Conversion Costs. Debt conversion costs for the year ended December 31, 2010 totaled $141,000 compared to $819,000 for the same period in 2009. During the year ended December 31, 2009, we entered into exchange agreements with the 4.50% and 7.00% Note holders that included a more favorable conversion rate compared to the original conversion rates under the terms of the 4.50% and 7.00% Notes.

***Reorganization Items*.** Reorganization items for the year ended December 31, 2010 totaled $1,677,000 compared to $2,066,000 for the same period in 2009. Reorganization items include professional advisory fees and other costs directly associated with our Chapter 11 bankruptcy activities.

Reorganization Items Related Party Incentive Plan. Reorganization items for the year ended December 31, 2010 amounted to $6,932,000. We paid $5,000,000 in cash and accrued $1,932,000 for the value of the vested portions of restricted stock under the Incentive Plan prior to us emerging from bankruptcy under the Bankruptcy Code.

***Other Income (Expense), Net*.** Net other income was $358,000 for the year ended December 31, 2010 compared to $20,000 of expense for the same period in 2009. Other income for the year ended December 31, 2010 included an award of two grants for the aggregate sum of $489,000 under the Internal Revenue Service Qualifying Therapeutic Discovery Projects Grant Program for the OVA2 and PAD programs.

***Income Tax Benefit (Expense)*.** There was no income tax benefit or expense for the year ended December 31, 2010 compared to income tax expense of $11,000 for the same period in 2009. Income tax expense in 2009 was due to foreign income taxes.

Liquidity and Capital Resources

On March 9, 2010, we commercially launched OVA1. We will continue to expend resources in the selling and marketing of OVA1 and developing additional diagnostic tests.

On February 18, 2011, we completed an underwritten follow-on public offering of our common stock for net proceeds of $20,206,000 after deducting underwriting discounts and offering expenses. Our $5,000,000 of outstanding 7.00% Notes due in September 2011 were paid in full.

We have incurred significant net losses and negative cash flows from operations since inception. At December 31, 2011, we had an accumulated deficit of $316,299,000 and stockholders equity of $10,359,000. On December 31, 2011, we had $22,477,000 of cash and cash equivalents and $11,476,000 of current liabilities including $7,000,000 principal amount under a secured line of credit from Quest Diagnostics due and payable on October 7, 2012.

We expect cash for OVA1 from Quest Diagnostics to be our only material, recurring source of cash in 2012. In order to continue our operations as currently planned through 2013 and beyond, we will need to raise additional capital. Given the above conditions, there is substantial doubt about the Company s ability to continue as a going concern.

The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

The successful achievement of our business objectives will require additional financing and therefore, we will need to raise additional capital or incur indebtedness to continue to fund our future operations. We will 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. If we obtain additional funds through arrangements with collaborators or strategic partners, we may be required to relinquish our rights to certain technologies or products that we might otherwise

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seek to retain. Additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may be required to delay, reduce the scope of or eliminate our sales and marketing and/or research and development activities.

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

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

Cash and cash equivalents as of December 31, 2011 and December 31, 2010 were $22,477,000 and $22,914,000, respectively. At December 31, 2011 and 2010, working capital was $11,417,000 and $13,726,000, respectively.

Net cash used in operating activities was $15,581,000 for the year ended December 31, 2011, resulting primarily from operating losses incurred as adjusted for a change in fair value of warrants of $378,000 and non-cash license revenues of $454,000, partially offset by $3,286,000 of stock-based compensation expense.

Net cash used in operating activities was $20,935,000 for the year ended December 31, 2010, resulting primarily from operating losses incurred as adjusted for a change in fair value of warrants and warrant exercises of $4,353,000 and non-cash license revenues of $867,000, partially offset by $141,000 in debt conversion costs, $114,000 of depreciation and amortization, $1,900,000 of stock-based compensation expense and $4,969,000 of Debtor s Incentive Plan charges with related parties. Net cash used in operating activities also decreased by $3,803,000 of cash provided by changes in operating assets and liabilities mainly driven by the $3,928,000 in reorganization items.

Net cash used in investing activities was $99,000 for the year ended December 31, 2011, due to the purchase of property and equipment.

Net cash provided by investing activities was $350,000 for the year ended December 31, 2010, primarily due to the proceeds from the sale of investments of $465,000 and the maturity of a certificate of deposit pledged as collateral on a letter of credit of $60,000 partially offset by $180,000 purchase of property and equipment.

Net cash provided by financing activities was $15,240,000 for the year ended December 31, 2011, which resulted primarily from net proceeds of $20,206,000 in connection with our February 2011 follow-on public offering partially offset by our $5,000,000 repayment of our 7.00% Senior Convertible Notes in September 2011.

Net cash provided by financing activities was $40,050,000 for the year ended December 31, 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.

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Contractual Obligations

The following summarizes our contractual obligations at December 31, 2011, including the extension of our Austin, TX principal facility operating lease in March 2012, and the effect such obligations are expected to have on our liquidity and cash flow in future periods:

(in thousands)	Total	2012	2013	Thereafter
Loan from Quest Diagnostics Inc.[1]	$ 7,000	$ 7,000		$
Interest payable on loan from Quest Diagnostics Inc.[2]	202	202		
Noncancelable collaboration obligations[3]	563	450	113	
Noncancelable operating lease obligations	161	121	40	
Purchase obligations				
Total contractual obligations	$ 7,926	$ 7,773	$ 153	$

(1) Principal amounts, not including interest.
(2) Based on outstanding principal balance and interest rate as of December 31, 2011.
(3) The following are non-cancelable collaboration obligations: Research collaboration agreement with the Johns Hopkins University School of Medicine and Stanford University.

Off-Balance Sheet Arrangements

As of December 31, 2011, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, including consolidated balance sheets as of December 31, 2011 and 2010, consolidated statements of operations for the years ended December 31, 2011 and 2010, consolidated statements of changes in stockholders equity (deficit) and comprehensive loss for the years ended December 31, 2011 and 2010, consolidated statements of cash flows for the years ended December 31, 2011 and 2010 and notes to our consolidated financial statements, together with a report thereon of our independent registered public accounting firm, dated March 26, 2012, are attached hereto as pages F-1 through F-31.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and

Principal Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure.

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An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act, as of December 31, 2011.

Based on that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of December 31, 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.

Management Report on Internal Control over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over our financial reporting. We have assessed the effectiveness of internal control over financial reporting as of December 31, 2011. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP). Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on using the COSO criteria, management concluded our internal control over financial reporting as of December 31, 2011 was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2011, was not subject to attestation by our independent registered public accounting firm pursuant to rules of the United States Securities and Exchange Commission (SEC) that permit a smaller reporting company to provide only management s report in this Annual Report on Form 10-K.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding our Directors, committees of our Board of Directors, including our audit committee and nominating and corporate governance committee, our Director nomination process, and our Executive Officers appearing under the heading Information Regarding the Board of Directors, Committees and Corporate Governance, Management and Section 16(a) Beneficial Ownership Reporting Compliance, of our proxy statement relating to our 2012 Annual Meeting of Stockholders to be held on June 7, 2012 (the 2012 Proxy Statement) is incorporated by reference.

Our code of ethics is applicable to all employees, including both our President and Chief Executive Officer and Principal Financial Officer. This code of ethics is publicly available on our website at http://www.vermillion.com. If our Board makes any amendments to this code other than technical, administrative or other non-substantive amendments, or grants any waivers, including implicit waivers, from a provision of this code to any officer or person described in paragraph (a) of Item 5.05 of Form 8-K, we will disclose the nature of the amendment or waiver, its effective date and to whom it applies on our website.

ITEM 11. EXECUTIVE COMPENSATION

The information appearing under the headings Board Compensation, Compensation Discussion and Analysis, Executive Officer Compensation, Corporate Governance Compensation Committee Interlocks and Insider Participation and Report of the Compensation Committee of the 2012 Proxy Statement is incorporated by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information appearing under the heading Security Ownership of Certain Beneficial Owners and Management of the 2012 Proxy Statement is incorporated by reference.

See the description regarding our equity compensation plans contained in the notes to our financial statements, attached hereto.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information appearing under the heading Certain Relationships and Related Transactions and Information Regarding the Board of Directors, Committees and Corporate Governance of the 2012 Proxy Statement is incorporated by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information appearing under the heading Ratification of the Selection of the Independent Public Accounting Firm for Vermillion of the 2012 Proxy Statement is incorporated by reference.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) LIST OF DOCUMENTS FILED AS PART OF THIS REPORT:

1. *Financial Statements*

The financial statements and notes thereto, and the report of the independent registered public accounting firm thereon, are set forth on pages F-1 through F-31.

2. *Exhibits*

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Vermillion, Inc.

Date: March 26, 2012

/s/ GAIL S. PAGE
Gail S. Page
President and Chief Executive Officer

(Principal Executive Officer)

Date: March 26, 2012

/s/ ERIC J. SCHOEN
Eric J. Schoen
Chief Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ GAIL S. PAGE **Gail S. Page**	President and Chief Executive Officer (Principal Executive Officer)	March 26, 2012
/s/ ERIC J. SCHOEN **Eric J. Schoen**	Chief Accounting Officer (Principal Financial Officer)	March 26, 2012
/s/ JAMES S. BURNS **James S. Burns**	Chairman of the Board of Directors	March 26, 2012
/s/ JOHN F. HAMILTON **John F. Hamilton**	Director	March 26, 2012
/s/ BRUCE A. HUEBNER **Bruce A. Huebner**	Director	March 26, 2012
/s/ PETER S. RODDY **Peter S. Roddy**	Director	March 26, 2012
/s/ CARL SEVERINGHAUS **Carl Severinghaus**	Director	March 26, 2012
/s/ WILLIAM C. WALLEN, PH.D.	Director	March 26, 2012

William C. Wallen, Ph.D.

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INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	Findings of Fact, Conclusions of Law and Order Confirming Debtor s (Vermillion Inc. s) Second Amended Plan of Reorganization Under Chapter 11 of the Bankruptcy Code dated January 7, 2010	8-K	000-31617	2.1	January 12, 2010	
3.1	Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated January 22, 2010	8-K	000-31617	3.1	January 25, 2010	
3.2	Third Amended and Restated Bylaws of Vermillion, Inc.					ü
4.1	Form of Vermillion, Inc. s (formerly Ciphergen Biosystems, Inc.) Common Stock Certificate	S-1/A	333-32812	4.1	August 24, 2000	
4.2	Preferred Shares Rights Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Continental Stock Transfer & Trust Company dated March 20, 2002	8-A	000-31617	4.2	March 21, 2002	
4.3	Amendment to Rights Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Wells Fargo Bank, N.A. dated July 22, 2005	8-K	000-31617	4.4	July 28, 2005	
4.4	Second Amendment to Rights Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Wells Fargo Bank, N.A. dated September 30, 2005	8-K	000-31617	4.5	October 4, 2005	
4.5	Third Amendment to Rights Agreement between Vermillion, Inc. and Wells Fargo Bank, N.A., dated September 11, 2007	8-K	000-31617	10.1	September 12, 2007	
10.1	1993 Stock Option Plan #	S-1	333-32812	10.3	March 20, 2000	
10.2	Form of Stock Option Agreement #	S-1/A	333-32812	10.4	August 24, 2000	
10.3	2000 Stock Plan and related form of Stock Option Agreement #	S-1/A	333-32812	10.5	August 4, 2000	
10.4	Amended and Restated 2000 Employee Stock Purchase Plan #	10-Q	000-31617	10.6	November 14, 2007	
10.5	Vermillion, Inc. 2010 Stock Incentive Plan #	8-K	000-31617	10.1	February 12, 2010	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.6	Ciphergen Biosystems, Inc. 401(k) Plan #	10-K	000-31617	10.7	March 22, 2005	
10.7	Securities Purchase Agreement by and among Vermillion, Inc. and the purchasers party thereto dated August 23, 2007	S-1	333-146354	10.57	September 27, 2007	
10.8	Form of Warrant	10-Q	000-31617	10.51	November 14, 2007	
10.9	Form of Securities Purchase Agreement between Vermillion, Inc. and the purchasers party thereto dated December 24, 2009	8-K	000-31617	10.1	December 29, 2009	
10.10	Employment Agreement between Sandra A. Gardiner and Vermillion, Inc. dated April 9, 2010 #	8-K	000-31617	10.1	April 22, 2010	
10.11	Employment Agreement between Gail S. Page and Vermillion, Inc. dated September 28, 2010 #	8-K	000-34810	10.1	September 30, 2010	
10.12	Employment Agreement between Eric T. Fung and Vermillion, Inc. dated September 28, 2010 #	8-K	000-34810	10.2	September 30, 2010	
10.13	Form of Severance Agreement between key executive employees and Vermillion, Inc. #	8-K	000-31617	10.1	August 29, 2008	
10.14	Form of Proprietary Information Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and certain of its employees #	S-1/A	333-32812	10.9	August 24, 2000	
10.15	Consulting Agreement between Richard G. Taylor and Vermillion, Inc. dated August 26, 2008 #	8-K	000-31617	10.1	August 29, 2008	
10.16	MAS License Agreement with IllumeSys Pacific, Inc. dated April 7, 1997	S-1/A	333-32812	10.23	August 24, 2000	
10.17	MAS License Agreement with Ciphergen Technologies, Inc. (formerly ISP Acquisition Corporation) dated April 7, 1997	S-1	333-32812	10.24	August 24, 2000	
10.18	Settlement Agreement and Mutual General Release by and among Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.), IllumeSys Pacific, Inc., Ciphergen Technologies, Inc., Molecular Analytical Systems, Inc., LumiCyte, Inc. and T. William Hutchens dated May 28, 2003	8-K	000-31617	99.2	June 11, 2003	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.19	Assignment Agreement by and among Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.), IllumeSys Pacific, Inc., Ciphergen Technologies, Inc., Molecular Analytical Systems, Inc., LumiCyte, Inc. and T. William Hutchens dated May 28, 2003	8-K	000-31617	99.3	June 11, 2003	
10.20	License Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Molecular Analytical Systems, Inc. dated May 28, 2003	8-K	000-31617	99.4	June 11, 2003	
10.21	Collaborative Research Agreement between University College London, UCL Biomedica plc and Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) dated September 22, 2005	10-K	000-31617	10.54	March 17, 2006	
10.22	Distribution and Marketing Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Ciphergen Biosystems KK dated March 24, 1999	S-1/A	333-32812	10.26	September 22, 2000	
10.23	Strategic Alliance Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.44	July 28, 2005	
10.24	Amendment to Strategic Alliance Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated October 7, 2009	8-K	000-31617	10.2	October 21, 2009	
10.25	Amendment to Strategic Alliance Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated November 10, 2010	8-K	000-34810	10.1	November 12, 2010	
10.26	Amendment No. 5 to Strategic Alliance Agreement by and among Vermillion, Inc. and Quest Diagnostics Incorporated and Quest Diagnostics India Private Limited, dated April 2, 2011	10-Q	001-34810	10.1	May 10, 2011	
10.27	Stock Purchase Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.45	July 28, 2005	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.28	Warrant between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.46	July 22, 2005	
10.29	Amendment to Warrant between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated August 29, 2007	8-K	000-31617	10.2	August 29, 2007	
10.30	Letter Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated August 29, 2007	S-1	333-146354	10.38	September 27, 2007	
10.31	Credit Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.47	July 28, 2005	
10.32	Debtor-In-Possession Credit and Security Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated October 7, 2009	8-K	000-31617	10.1	October 21, 2009	
10.33	Memorialization Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated January 12, 2006	S-1	333-146354	10.40	September 27, 2007	
10.34	Patent Security Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.48	July 28, 2005	
10.35	Asset Purchase Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated August 14, 2006	14a	000-31617	Annex A	September 12, 2006	
10.36	Amendment to Asset Purchase Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1	333-146354	10.47	September 27, 2007	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.37	Stock Purchase Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1	333-146354	10.48	September 27, 2007	
10.38	Transition Services Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1/A	333-146354	10.53	November 27, 2007	
10.39	Amendment No. 1 to Transition Services Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated May 11, 2007	S-1	333-146354	10.50	September 27, 2007	
10.40	Amendment No. 2 to Transition Services Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated June 15, 2007	S-1	333-146354	10.51	September 27, 2007	
10.41	Manufacture and Supply Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1/A	333-146354	10.56	November 27, 2007	
10.42	Amendment No. 1 to Manufacture and Supply Agreement between Vermillion, Inc. and Bio-Rad Laboratories, Inc. dated August 27, 2007	S-1	333-146354	10.53	September 27, 2007	
10.43	Cross License Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1/A	333-146354	10.58	November 27, 2007	
10.44	Sublicense Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1	333-146354	10.13	September 27, 2007	
10.45	Letter Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1	333-146354	10.55	September 27, 2007	

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Exhibit		Incorporated by Reference				Filed
Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Herewith
10.46	Sublease Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1/A	333-146354	10.60	November 27, 2007	
10.47	Exclusive Distribution Agreement between Vermillion, Inc. and Pronto Diagnostics Ltd., dated August 1, 2011	10-Q	001-34810	10.1	August 9, 2011	
10.48	Consulting Agreement between Vermillion, Inc. and Bruce A. Huebner, dated June 17, 2011#	10-Q	001-34810	10.2	August 9, 2011	
10.49	Consulting Agreement between Vermillion, Inc. and Eric T. Fung, dated November 4, 2011#	10-Q	001-34810	10.1	November 9, 2011	
10.50	Asset Purchase Agreement between Vermillion, Inc. and Correlogic Systems, Inc., dated November 8, 2011					ü
10.51	Settlement Agreement and Release between Vermillion, Inc. and a third party, dated February 9, 2012					ü
14.1	Code of Ethics	8-K	001-34810	14.1	December 7, 2010	
21.0	Subsidiaries of Registrant					ü
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm					ü
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					ü
31.2	Certification of the Chief Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					ü
32.0	Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					(1)
101.INS	XBRL Instance Document					(1)
101.SCH	XBRL Taxonomy Extension Schema Document					(1)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					(1)

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date	Filed Herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					(1)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					(1)

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

(1) Furnished herewith

Management contracts or compensatory plan or arrangement.

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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VERMILLION, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Vermillion, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Vermillion, Inc. and its subsidiaries (the Company) at December 31, 2011 and 2010, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the consolidated financial statements, the Company voluntarily filed for Chapter 11 bankruptcy protection on March 30, 2009 and subsequently emerged from bankruptcy on January 22, 2010.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations and has debt outstanding due and payable in October 2012, all of which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

Austin, Texas

March 26, 2012

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Vermillion, Inc.

Consolidated Balance Sheets

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

	December 31, 2011	2010
Assets		
Current assets:		
Cash and cash equivalents	$ 22,477	$ 22,914
Accounts receivable	99	136
Prepaid expenses and other current assets	317	779
Total current assets	22,893	23,829
Property and equipment, net	216	194
Other assets	2	12
Total assets	$ 23,111	$ 24,035
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,331	$ 998
Accrued liabilities	2,592	3,056
Short-term debt	7,000	
Convertible senior notes		5,000
Deferred revenue	553	1,049
Total current liabilities	11,476	10,103
Non-current liabilities:		
Long-term debt		7,000
Warrant liability		378
Long-term deferred revenue	1,224	1,679
Other liabilities	52	259
Total liabilities	12,752	19,419
Commitments and contingencies (Note 9)		
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2011 and 2010		
Common stock, $0.001 par value, 150,000,000 shares authorized; 14,900,831 and 10,657,564 shares issued and outstanding at December 31, 2011 and 2010, respectively	15	11
Additional paid-in capital	326,796	303,270
Accumulated deficit	(316,299)	(298,509)
Accumulated other comprehensive loss	(153)	(156)
Total stockholders equity	10,359	4,616
Total liabilities and stockholders equity	$ 23,111	$ 24,035

See accompanying Notes to Consolidated Financial Statements

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Vermillion, Inc.

Consolidated Statements of Operations

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

	Year Ended December 31, 2011	2010
Revenue:		
Product	$ 1,469	$ 308
License	454	867
Total revenue	1,923	1,175
Cost of revenue:		
Product	129	88
Total cost of revenue	129	88
Gross profit	1,794	1,087
Operating expenses:		
Research and development[(1)]	5,387	3,848
Sales and marketing[(2)]	5,539	2,857
General and administrative[(3)]	8,509	8,984
Total operating expenses	19,435	15,689
Loss from operations	(17,641)	(14,602)
Interest income	64	40
Interest expense	(396)	(491)
Gain on investments in auction rate securities		58
Change in fair value and gain from warrant exercise, net	378	4,353
Debt conversion costs		(141)
Reorganization items	(96)	(1,677)
Reorganization items related party incentive plan		(6,932)
Other income (expense), net	(99)	358
Loss before income taxes	(17,790)	(19,034)
Income tax benefit (expense)		
Net loss	$ (17,790)	$ (19,034)
Net loss per share basic and diluted	$ (1.25)	$ (1.83)
Weighted average common shares used to compute basic and diluted net loss per common share	14,249,570	10,404,741
Non-cash stock-based compensation expense included in operating expenses:		
(1) Research and development	$ 686	$ 992
(2) Sales and marketing	158	77
(3) General and administrative	2,446	3,868

See accompanying Notes to Consolidated Financial Statements

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Vermillion, Inc.

Consolidated Statements of Changes in Stockholders Equity (Deficit) and Comprehensive Loss

(Amounts in Thousands, Except Share Amounts)

	Common Stock		Additional		Accumulated Other	Total	
	Shares	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Loss	Stockholders Equity (Deficit)	Comprehensive Loss
Balance at December 31, 2009	7,918,705	8	252,196	(279,475)	(46)	(27,317)	
Net loss				(19,034)		(19,034)	$ (19,034)
Change in unrealized gain(loss) on auction rate securities					(119)	(119)	(119)
Foreign currency translation adjustment					9	9	9
Comprehensive loss							$ (19,144)
Common stock issued in conjunction with private placement sale, net of issuance costs	2,327,869	2	42,780			42,782	
Common stock issued in conjuntion with execise of stock options	21,083		42			42	
Warrant exercises, net of issuance cost	46,972		926			926	
Conversion of convertible senior notes, net of issuance cost	16,283		458			458	
Common stock issued for debtor's incentive plan	226,904		4,969			4,969	
Common stock issued for restricted stock awards	99,748	1	535			536	
Stock compensation charge			1,364			1,364	
Balance at December 31, 2010	10,657,564	11	303,270	(298,509)	(156)	4,616	
Net loss				(17,790)		(17,790)	$ (17,790)
Foreign currency translation adjustment					3	3	3
Comprehensive loss							$ (17,787)
Common stock issued in conjunction with follow-on public offering, net of issuance costs	4,000,000	4	20,202			20,206	
Common stock issued in conjuntion with execise of stock options	21,833		34			34	
Common stock issued for debtor's incentive plan	75,637		1,656			1,656	
Common stock issued for restricted stock awards	145,797		587			587	
Warrants issued for services			4			4	
Stock compensation charge			1,043			1,043	
Balance at December 31, 2011	14,900,831	$ 15	$ 326,796	$ (316,299)	$ (153)	$ 10,359	

See accompanying Notes to Consolidated Financial Statements

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Vermillion, Inc.

Consolidated Statements of Cash Flows

(Amounts in Thousands)

	Year Ended December 31, 2011	2010
Cash flows from operating activities:		
Net loss	$ (17,790)	$ (19,034)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of investments		(58)
Change in fair value and gain from warrant exercise, net	(378)	(4,353)
Common stock issued for debtor's incentive plan with related parties		4,969
Non-cash license revenue	(454)	(867)
Debt conversion costs		141
Loss on sale and disposal of property and equipment		56
Depreciation and amortization	77	114
Stock-based compensation expense	3,286	1,900
Warrants issued for services	4	
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	37	(136)
Decrease (increase) in prepaid expenses and other current assets	462	(385)
Decrease (increase) in other assets	10	(12)
Increase in accounts payable and accrued liabilities	253	63
Increase (decrease) in deferred revenue	(497)	595
Decrease in other liabilities	(207)	
Reorganization items	(384)	(3,928)
Net cash used in operating activities	(15,581)	(20,935)
Cash flows from investing activities:		
Proceeds from sales of investments		465
Proceeds from sale of property and equipment		5
Purchase of property and equipment	(99)	(180)
Proceeds from maturity of CD pledged as collateral on letter of credit		60
Net cash (used in) / provided by investing activities	(99)	350
Cash flows from financing activities:		
Repayment of debtor-in-possession loan financing		(400)
Principal repayment of 7.00% convertible senior notes	(5,000)	
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	34	42
Costs related to issuance of common stock from warrant exercises		(133)
Issuance costs related to conversion of convertible senior notes		(46)
Net cash provided by financing activities	15,240	40,050
Effect of exchange rate changes on cash and cash equivalents	3	9
Net increase (decrease) in cash and cash equivalents	(437)	19,474
Cash and cash equivalents, beginning of year	22,914	3,440
Cash and cash equivalents, end of year	$ 22,477	$ 22,914
Supplemental disclosure of cash flow information:		

Cash paid during the period for:		
Interest	$ 462	$ 1,407
Income taxes		
Non-cash investing and financing activities:		
Principal reduction from conversion of senior convertible notes	$	$ (170)
Principal reduction from forgiveness of Quest secured line of credit		(3,000)
Issuance of common stock from warrant exercise		1,059
Issuance of common stock from conversion of principal and interest for senior convertible notes		504

See accompanying Notes to Consolidated Financial Statements

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Vermillion, Inc.

Notes to Consolidated Financial Statements

NOTE 1: Basis of Presentation and Summary of 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 diagnostic tests in the fields of oncology, cardiology and women s health. On March 9, 2010, we commercially launched OVA1 ovarian tumor triage test (OVA1). As discussed in Note 4, we distribute OVA1 through Quest Diagnostics, which has the non-exclusive right to commercialize OVA1 on a worldwide basis, with exclusive commercialization rights in each exclusive territory, beginning on the date OVA1 was first commercialized and ending on the fifth anniversary of the date that OVA1 was cleared by the FDA, with the right to extend the exclusivity period for one additional year. These exclusive territories include the United States, India, Mexico, and the United Kingdom.

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 achieves certain minimum sales of OVA1 to maintain the exclusive distribution rights.

On December 19, 2011, we completed the purchase of substantially all of the assets of Correlogic Systems, Inc. (Correlogic) for $435,000. The purchase included certain documents, diagnostic samples and intellectual property owned by and licensed to Correlogic in connection with Correlogic s ovarian cancer diagnostics business, including a diagnostic test under the name OvaCheck for the detection of ovarian cancer. The purchase was expensed during the year ended December 31, 2011 as the assets acquired will be consumed in research and development activities, with no alternative future use.

Liquidity

On March 9, 2010, we commercially launched OVA1. We will continue to expend resources in the selling and marketing of OVA1 and developing additional diagnostic tests.

On February 18, 2011, we completed an underwritten follow-on public offering of our common stock for net proceeds of $20,206,000 after deducting underwriting discounts and offering expenses. Our $5,000,000 of outstanding 7.00% Notes due in September 2011 were paid in full.

We have incurred significant net losses and negative cash flows from operations since inception. At December 31, 2011, we had an accumulated deficit of $316,299,000 and stockholders equity of $10,359,000. On December 31, 2011, we had $22,477,000 of cash and cash equivalents and $11,476,000 of current liabilities including $7,000,000 principal amount under a secured line of credit from Quest Diagnostics due and payable on October 7, 2012.

We expect cash for OVA1 from Quest Diagnostics to be our only material, recurring source of cash in 2012. In order to continue our operations as currently planned through 2013 and beyond, we will need to raise additional capital. Given the above conditions, there is substantial doubt about the Company s ability to continue as a going concern. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments that might result from these uncertainties.

The successful achievement of our business objectives will require additional financing and therefore, we will need to raise additional capital or incur indebtedness to continue to fund our future operations. We will seek

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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. If we obtain additional funds through arrangements with collaborators or strategic partners, we may be required to relinquish our rights to certain technologies or products that we might otherwise seek to retain. Additional funding may not be available when needed or on terms acceptable to us. If we are unable to obtain additional capital, we may be required to delay, reduce the scope of or eliminate our sales and marketing and/or research and development activities.

Principals of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions have been eliminated in consolidation.

Basis of Presentation

The Financial Accounting Standards Board s (FASB) Accounting Standards Codification (ASC or Codification) 852, Reorganizations applied our financial statements while we operated under the provisions of Chapter 11. ASC 852 does not change the application of generally acceptable accounting principles in the United States of America (U.S. 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.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The primary estimates underlying our consolidated financial statements include assumptions regarding variables used in calculating the fair value of our equity awards, income taxes and contingent liabilities. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with maturities of three months or less from the date of purchase, which are readily convertible into known amounts of cash and are so near to their maturity that they present an insignificant risk of changes in value because of interest rate changes. Highly liquid investments that are considered cash equivalents include money market funds, certificates of deposits, treasury bills and commercial paper. The carrying value of cash equivalents approximates fair value due to the short-term maturity of these securities.

Fair Value Measurement

ASC 820, Fair Value and Measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

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Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

If a financial instrument uses inputs that fall in different levels of the hierarchy, the instrument will be categorized based upon the lowest level of input that is significant to the fair value calculation.

Concentration of Credit Risk

Financial instruments that potentially subject us to a concentration of credit risk consist of cash and cash equivalents and accounts receivable. We maintain the majority of our cash and cash equivalents in recognized financial institutions in the United States. We also maintain cash deposits with banks in China and Japan. We have not experienced any losses associated with our deposits of cash and cash equivalents. We do not invest in derivative instruments or engage in hedging activities.

Our accounts receivable are derived from sales made to a customer located in North America. We perform ongoing credit evaluations of our customer s financial condition and generally do not require collateral. We maintain an allowance for doubtful accounts based upon the expected collectability of accounts receivable. Our accounts receivable at December 31, 2011 and 2010 and revenues for the years then ended are from one active customer.

Property and Equipment

Property and equipment are carried at cost less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives, generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the remaining term of the lease. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations.

Property and equipment are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If property and equipment are considered to be impaired, an impairment loss is recognized.

Revenue Recognition

Product Revenue. We derive our product revenues from sales of OVA1 through Quest Diagnostics. We recognize product revenues for tests performed when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Accounts receivable from Quest Diagnostics Incorporated (Quest Diagnostics) totaled $85,000 and $121,000 at December 31, 2011 and 2010, respectively.

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License Revenue. Under the terms of the secured line of credit with Quest Diagnostics, portions of the borrowed principal amounts may be forgiven upon our achievement of certain milestones relating to the development, regulatory approval and commercialization of certain diagnostic tests (see Note 4). We account for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest Diagnostics receives upon commercialization of an approved diagnostic test as we do not have a meaningful history of product sales that provides a reasonable basis for estimating future product sales. We recognized license revenue on a straight-line basis over the 2.5-year period of Quest Diagnostics sales exclusivity beginning on OVA1 commercialization date of March 9, 2010 through November 10, 2010. On November 10, 2010, the period of Quest Diagnostics sales exclusivity for OVA1 was amended for up to three additional years. Accordingly, the balance of the principle amount forgiven at November 10, 2010 is recognized as license revenue on a straight-line basis over the amended term of exclusivity for OVA1 ending in September 2015. Through December 31, 2011, a total of $3,000,000 has been forgiven by Quest Diagnostics based upon milestone achievement.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist primarily of payroll and related costs, materials and supplies used in the development of new products, and fees paid to third parties that conduct certain research and development activities on our behalf. In addition, acquisitions of assets to be consumed in research and development are expensed as incurred as research and development costs. Software development costs incurred in the research and development of new products are expensed as incurred until technological feasibility is established.

Stock-Based Compensation

We record the fair value of non-cash stock-based compensation costs for stock options and stock purchase rights related to our 2010 Stock Incentive Plan (the 2010 Plan) and 2000 Stock Plan (the 2000 Plan). We estimate the fair value of stock options using a Black-Scholes option valuation model. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. We use the straight-line method to amortize the fair value over the vesting period of the award. These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore are subject to management s judgment.

The expected life of options is based on historical data of our actual experience with the options we have granted and represents the period of time that the options granted are expected to be outstanding. This data includes employees expected exercise and post-vesting employment termination behaviors. The expected stock price volatility is estimated using a combination of historical and peer group volatility for a blended volatility in deriving the expected volatility assumption. We made an assessment that blended volatility is more representative of future stock price trends than just using historical or peer group volatility, which corresponds to the expected life of the options. The expected dividend yield is based on the estimated annual dividends that we expect to pay over the expected life of the options as a percentage of the market value of our common stock as of the grant date. The risk-free interest rate for the expected life of the options granted is based on the United States Treasury yield curve in effect as of the grant date.

We also record the fair value of non-cash stock-based compensation costs for equity instruments issued to non-employees. We recalculate costs for these options each reporting period using a Black-Scholes option valuation model. Because we recalculate these costs each reporting period, changes in assumptions used in our calculations, including changes in the fair value of our common stock, can result in significant changes in the amounts we record from one reporting period to another.

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Contingencies

We account for contingencies in accordance with ASC 450 Contingencies (ASC 450). ASC 450 requires that an estimated loss from a loss contingency shall be accrued when information available prior to issuance of the financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and when the amount of the loss can be reasonably estimated. Accounting for contingencies such as legal and contract dispute matters requires us to use our judgment. We believe that our accruals for these matters are adequate. Nevertheless, the actual loss from a loss contingency might differ from our estimates.

Income Taxes

We account for income taxes using the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and the tax bases of assets and liabilities using the current tax laws and rates. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts more likely than not expected to be realized.

Financial Interpretation (FIN) 48, Accounting for Uncertainty in Income Taxes , (codified primarily in FASB ASC Topic 740-10-50, Accounting for Uncertainty in Income Taxes) clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with Statement of Financial Accounting Standards (SFAS) 109, Accounting for Income Taxes (codified primarily in FASB ASC Topic 740, Income Taxes). ASC Topic 740-10-50 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition threshold at the effective date to be recognized upon the adoption of ASC Topic 740-10-50 and in subsequent periods. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

We recognize interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations. Accrued interest and penalties are included within the related liability lines in the consolidated balance sheet.

Foreign Currency Translation

The functional currency of Ciphergen Biosystems KK, a wholly owned subsidiary, is the Japanese yen. Accordingly, all balance sheet accounts of this operation are translated into United States dollars using the current exchange rate in effect at the balance sheet date. The expenses of Ciphergen Biosystems KK are translated using the average exchange rates in effect during the period, and the gains and losses from foreign currency translation are recorded in accumulated other comprehensive loss.

The functional currency of all other foreign operations is the United States dollar. Accordingly, all foreign currency denominated monetary assets and liabilities of these foreign operations are remeasured in United States dollars at exchange rates in effect at the balance sheet date and non-monetary assets and related elements of expense are remeasured using historical rates of exchange. Income and expense elements are remeasured in United States dollars using average exchange rates in effect during the period. Gains and losses from the foreign currency transactions of these subsidiaries are recorded as other income (expense).

Other Income

On November 2, 2010, we received notice of an award of two grants for the aggregate sum of $489,000 under the Internal Revenue Service Qualifying Therapeutic Discovery Projects Grant Program for our ongoing cancer related and peripheral arterial disease (PAD) programs. The grant relates to fiscal 2010 expenditures and was awarded to therapeutic or diagnostic discovery projects that show a reasonable potential to result in new therapies or diagnostic tests that address areas of unmet medical need or that prevent, detect or treat chronic or acute diseases and conditions. These grants were included in other income for the year ended December 31, 2010 and were recorded as other current assets at December 31, 2010. We received payment for these grants on February 3, 2011.

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Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss consists of unrealized gain (losses) from available-for-sale securities and foreign currency translation adjustment.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common stock shares outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of common stock shares adjusted for the dilutive effect of common stock equivalent shares outstanding during the period. Common stock equivalents consist of convertible senior notes (using the as if converted method), stock options, restricted stock units and stock warrants. Common equivalent shares are excluded from the computation in periods in which they have an anti-dilutive effect on earnings per share.

Fair Value of Financial Instruments

Financial instruments include cash and cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities, convertible senior notes and the amount owed on a secured line of credit with Quest Diagnostics. The estimated fair value of financial instruments has been determined using available market information or other appropriate valuation methodologies. However, considerable judgment is required in interpreting market data to develop estimates of fair value; therefore, the estimates are not necessarily indicative of the amounts that could be realized or would be paid in a current market exchange. The effect of using different market assumptions and/or estimation methodologies may be material to the estimated fair value amounts. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities are at cost, which approximates fair value due to the short maturity of those instruments. We believe the fair value of our debt at December 31, 2011 approximates its carrying value due to the short term to the debt s maturity in October 2012 and variable rate of interest (prime plus 0.5%).

Certain of our outstanding warrants are classified as liabilities in accordance with ACS 815 Derivatives and Hedging . We fair value these stock warrants at each reporting period, with the changes in fair value recognized in our consolidated statement of operations. We fair value the warrants using a Black Scholes valuation model. Since the outstanding common stock warrants are fair valued at the end of each reporting period, any change in the underlying assumptions to the Black Scholes valuation model, including the volatility and price of our common stock, may have a significant impact on our consolidated financial statements.

Segment Reporting

We operate one reportable segment, novel diagnostic tests.

NOTE 2: CHAPTER 11 BANKRUPTCY

On March 30, 2009, we filed a voluntary petition for relief under Chapter 11 in the Bankruptcy Court. We operated our business and managed our properties as debtors in possession 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 under Chapter 11 and our Bankruptcy Filing was formally closed on January 19, 2012.

Financial Statement Presentation

Our consolidated financial statements have been prepared in accordance with ASC 852, Reorganizations (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.

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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. Certain actions within the non-Debtor companies have occurred as a result of the Chapter 11 bankruptcy proceedings. In addition, we have made adjustments to the carrying value of certain pre-petition liabilities. The costs associated with these actions are also reported as reorganization items. The reorganization items in the consolidated statement of operations at December 31, 2011 and 2010 consisted of the following items:

(in thousands)	Year Ended December 31, 2011	2010
Debtors reorganization items		
Professional fees associated with bankruptcy proceedings	$ 80	$ 928
Related party incentive plan		6,932
Debtors reorganization items	$ 80	$ 7,860
Non-Debtors reorganization items		
Professional fees associated with bankruptcy proceedings	$ 16	$ 749
Total reorganization items	$ 96	$ 8,609

Plan of Reorganization

On January 7, 2010, the Bankruptcy Court issued a confirmation order approving our Plan of Reorganization. The Plan of Reorganization contemplates 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 secured line of credit was reinstated and unimpaired. Holders of the outstanding 4.50% Convertible Senior Notes due in 2009 received the payment of $2,195,000 of principal, $140,000 of unpaid interest and 9,044 shares of common stock in exchange of their claims. $5,000,000 in principal of the outstanding 7.00% Convertible Senior Notes due in 2011 were reinstated. 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.

On January 22, 2010, the confirmation order issued by the Bankruptcy Court 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. Our Bankruptcy Filing was formally closed on January 19, 2012.

NOTE 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,

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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, results of operations or cash flows but it will impact the way we present comprehensive income.

NOTE 4: Strategic Alliance with Quest Diagnostics Incorporated

Quest Diagnostics is a significant holder of our common stock. On July 22, 2005, we entered into a strategic alliance agreement (the Strategic Alliance Agreement) with Quest Diagnostics to develop and commercialize up to three diagnostic tests from our product pipeline (the Strategic Alliance). The Strategic Alliance Agreement was set to expire on the earlier of (i) the three-year anniversary of the agreement, which was July 22, 2008, and (ii) the date on which Quest Diagnostics commercializes three diagnostic tests. On July 21, 2008, the Strategic Alliance Agreement was amended to extend the term of the agreement to end on the earlier of (i) September 1, 2008 and (ii) the date on which Quest Diagnostics commercializes three diagnostic tests. On October 24, 2008, the Strategic Alliance Agreement was amended to extend the term of the agreement to end on the earlier of (i) September 1, 2009 and (ii) the date on which Quest Diagnostics makes its third development election. 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 makes its third development election. On November 10, 2010, we further amended the Strategic Alliance Agreement to give Quest Diagnostics the exclusive right to commercialize OVA1 for two additional years from the period as specified in the Strategic Alliance Agreement, with an option to extend such exclusive period in its sole discretion for one additional year, and to establish royalties, fees, and other payments related to the performance of OVA1. To date, Quest Diagnostics has selected two diagnostic tests to commercialize, our peripheral arterial disease blood test (VASCLIR) which is under development and OVA1. On April 2, 2011, we entered into Amendment No. 5 (the Strategic Alliance Agreement and the July 21, 2008, October 24, 2008, October 7, 2009, November 10, 2010 and April 2, 2011 amendments are collectively referred to as the Amended Strategic Alliance Agreement) with Quest Diagnostics and 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. The Amendment also establishes amounts due to Vermillion related to the performance of OVA1 in India.

Secured Line of Credit with Quest Diagnostics Incorporated

In connection with the Strategic Alliance Agreement, Quest Diagnostics provided us with a $10,000,000 secured line of credit, which is collateralized by certain of our intellectual property and may only be used for payment of certain costs and expenses directly related to the Strategic Alliance. Under the terms of this secured line of credit, the interest rate is at the prime rate plus 0.5% and is payable monthly. The effective interest rate was 3.75% at December 31, 2011 and 2010. This secured line of credit also contains provisions for Quest Diagnostics to forgive portions of the amounts borrowed that corresponds 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 that 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 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.

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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 have drawn on this secured line of credit in monthly increments of $417,000 on the last day of each month during the first two years of the Strategic Alliance. The outstanding principal balance of this secured line of credit was $7,000,000 at December 31, 2011 and 2010. Interest expense related to this secured line of credit was $263,000 and $278,000 for the years ended December 31, 2011 and 2010, respectively. From the inception of the Strategic Alliance through December 31, 2008, we spent $10,000,000 of the amounts drawn on in-house research and development, as well as collaborations with others, directed towards achieving the milestones. On September 11, 2009, we achieved the FDA clearance of OVA1 milestone provision in the secured line of credit agreement providing for a reduction in the principal amount of the loan of $3,000,000 but was only able to apply the milestone once it was no longer in default under the terms of the secured line of credit while under Chapter 11 bankruptcy protection. On January 22, 2010 we cured the default upon payment of accrued interest totaling approximately $472,000. On January 23, 2010, the principal was reduced to $7,000,000. We are in discussions with Quest Diagnostics regarding the achievement of an additional $1,000,000 forgiveness milestone as a result of the FDA clearance of OVA1 under the terms of the Strategic Alliance Agreement. However, Quest Diagnostics has not acknowledged that such milestone has been achieved.

NOTE 5: Fair Value Measurements

Historically, our investments consisted of auction rate securities, which were classified as available-for-sale long-term investments due to failed auctions related to these investments through December 31, 2009.

On July 26, 2010, we sold the auction rate securities investments for total proceeds of $465,000 and recorded a realized gain on investment of $58,000 for the year ended December 31, 2010. We did not hold any short or long term investments at December 31, 2011.

We measure certain common stock warrants at fair value on a recurring basis (see Note 10). All other financial assets and liabilities are measured at fair value on a nonrecurring basis. These financial assets and liabilities are recognized at fair value when they are deemed to be other-than-temporarily impaired.

The reconciliation of financial assets measured at fair value using significant unobservable inputs (Level 3) for the years ended December 31, 2011 and 2010 was as follows:

(in thousands)	Long-Term Investments Available-for-Sale (Level 3) Auction Rate Securities
Balance at January 1, 2010	$ 526
Total realized gains included in earnings	58
Change in unrealized gain(loss) included in other comprehensive loss	(119)
Sales	(465)
Balance at December 31, 2010	$

We determine the fair value of our debt based on the then-current rates available to us for debt of a similar term and remaining maturity. We determined the estimated fair value amount by using available market information and commonly accepted valuation methodologies. We believe the fair value of our debt at December 31, 2011 approximates its carrying value due to the short term to the debt s maturity in October 2012 and variable rate of interest (prime plus 0.5%.

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NOTE 6: PROPERTY AND EQUIPMENT

The components of property and equipment as of December 31, 2011 and 2010 were as follows:

	December 31,	
(in thousands)	**2011**	**2010**
Machinery and equipment	$ 184	$ 123
Demonstration equipment	30	
Computer equipment and software	251	244
Furniture and fixtures	65	64
Gross property and equipment	530	431
Accumulated depreciation and amortization	(314)	(237)
Property and equipment, net	$ 216	$ 194

Depreciation expense for property and equipment was $77,000 and $114,000 for the years ended December 31, 2011 and 2010, respectively. During the year ended December 31, 2010, we disposed of significant fully depreciated assets in conjunction with our exit of our Fremont, California facility and move to Austin, Texas.

NOTE 7: ACCRUED LIABILITIES

The components of accrued liabilities as of December 31, 2011 and 2010 were as follows:

	December 31,	
(in thousands)	**2011**	**2010**
Payroll and benefits related expenses	$ 641	$ 596
Collaboration and research agreements expenses	303	276
Professional services	279	669
Contingencies	1,025	925
Tax-related liabilities	76	251
Accrued interest	238	304
Other accrued liabilities	30	35
Total accrued liabilities	$ 2,592	$ 3,056

NOTE 8: CONVERTIBLE SENIOR NOTES

7.00% Convertible Senior Notes Due September 1, 2011

On November 15, 2006, we closed the sale of $16,500,000 of convertible senior notes due September 1, 2011. Offering costs were $104,000 and fees of $514,500, which were paid on behalf of the debt holders, were recorded as debt discount on the 7.00% Notes. Fees paid on behalf of debt holders included the fair value of two warrants issued to underwriters to purchase a total of 20,000 shares of our common stock at $12.60 per share. The warrants were valued at $140,000 based on the fair value as determined by a Black-Scholes model using the following assumptions: a risk free interest rate of 4.75%, 5 year contractual life, and 88.00% volatility rate. The 7.00% Notes were sold pursuant to separate exchange and redemption agreements between Vermillion and each of Highbridge International LLC, Deerfield International Limited, Deerfield Partners, L.P., Bruce Funds, Inc. and Professional Life & Casualty, each holders of the existing 4.50% convertible senior notes due September 1, 2008, pursuant to which holders of an aggregate of $27,500,000 of the 4.50% Notes agreed to exchange and redeem their 4.50% Notes for an aggregate of $16,500,000 in aggregate principal amount of the 7.00% Notes and $11,000,000 in cash, plus accrued and unpaid interest on the 4.50% Notes of $254,000. Debt discount related to the 7.00% Notes was amortized to interest expense using the effective interest method. There was no amortization of the debt discount related to the 7.00% Notes for the years ended December 31, 2011 and 2010.

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The 7.00% Notes are unsecured senior indebtedness of Vermillion initially bearing interest at the rate of 7.00% per annum. The 7.00% Notes were reduced to 4.00% per annum on September 11, 2009 upon FDA clearance of OVA1.

The 7.00% Notes were convertible at the option of each holder prior to September 1, 2011 into shares of our common stock at a conversion price of $20.00 per share, equivalent to a conversion rate equal to 50 shares of our common stock per $1,000 principal of the 7.00% Notes, subject to adjustment for standard anti-dilution provisions including distributions to common stockholders and stock splits as well as occurrence of a change in control, in which case the conversion rate was to be adjusted for a make-whole premium. The conversion feature, including the make-whole premium, expired unexercised in September 2011.

Holders of the 7.00% Notes had the option to require us to repurchase the 7.00% Notes under certain circumstances, including at any time after September 1, 2009, if we did not receive approval or clearance for commercial sale of any of our ovarian cancer tests by the FDA. We could redeem the 7.00% Notes at our option, in whole or in part, after September 1, 2009, at specified redemption prices plus accrued and unpaid interest; provided that the 7.00% Notes will be redeemable only if the closing price of the stock equals or exceeds 200.0% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days ending on the trading day before the date of the notice of the optional redemption. Upon a change of control, each holder of the 7.00% Notes could have required us to repurchase some or all of the 7.00% Notes at specified redemption prices, plus accrued and unpaid interest. The 7.00% Notes contained a put option that entitles the holder to require us to redeem the 7.00% Notes at a price equal to 105.0% of the principal balance upon a change in control of the Company. These provisions expired with the repayment of the 7.00% Notes in September 2011.

We identified the guaranteed interest payment for any conversion of any 7.00% Note prior to October 31, 2008, and the written put option permitting the holder to put the debt at 105.0% of principal plus accrued and unpaid interest upon a change of control as embedded derivatives, which needed to be separated and measured at fair value. The factors impacting the fair value of the guaranteed interest payment for any conversion of any 7.00% Note prior to October 31, 2008, was based upon certain factors including our stock price, the time value of money and the likelihood holders would convert. The provision for the guaranteed interest payment for any conversion of any 7.00% Note lapsed on October 31, 2008. The factors impacting the fair value of the written put option permitting the holder to put the 7.00% Note at 105.0% of principal plus accrued and unpaid interest upon a change of control was contingent upon a change of control. However, due to significant related party holdings of our common stock shares and the presence of certain anti-takeover provisions in our bylaws, a change of control was deemed to be remote. Thus, the fair values of these features were determined to be de minimis from the date of their inception through the repayment of the debt in September 2011.

From October through November 2009, we exchanged a total of 220,000 shares of common stock for $4,400,000 in principal under the terms of the original 7.00% Notes. In November through December 2009, we exchanged a total of 421,667 shares of common stock for $7,100,000 in principal and $589,000 in unpaid interest. The conversion rate for the November and December 2009 redemption was approximately 55 shares per $1,000 principal amount. We recorded an additional debt conversion expense of $819,000 relating to the more favorable exchange rate during the year ended December 31, 2009.

The 7.00% Notes and common stock issuable upon conversion of the 7.00% Notes were registered with the SEC on Form S-3 on December 15, 2006. We were in default of the 7.00% Notes as of December 31, 2009. However, we cured the default upon payment of accrued interest totaling approximately $362,000 upon emergence from bankruptcy under Chapter 11 on January 22, 2010. At December 31, 2010, $5,000,000 in aggregate principal amount of the 7.00% Notes remained outstanding and the 7.00% Notes were repaid in full in September 2011.

4.50% Convertible Senior Notes Due September 1, 2009

On August 22, 2003, we closed the sale of $30,000,000 of the 4.50% Notes with an original maturity date of September 1, 2008. Offering costs were $1,866,000. Interest on the notes is 4.50% per annum on the principal amount. The effective interest rate was 6.28% per annum. The 4.50% Notes were convertible, at the option of the

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holder prior to maturity into shares of our common stock initially at a conversion rate of 10.88329 shares per $1,000 principal amount of the 4.50% Notes, which is equal to a conversion price of $91.88 per share. The conversion price, and hence the conversion rate, was subject to adjustment upon the occurrence of certain events, such as stock splits, stock dividends and other distributions or recapitalizations. Because the market value of the stock rose above the conversion price between the day the 4.50% Notes were priced and the closing date, we recorded a discount of $2,677,000 related to the intrinsic value of the beneficial conversion feature resulting from this price change and the fact that the initial purchaser of the 4.50% Notes was not required to purchase the 4.50% Notes until the closing date. Immediately after the closing, our common stock had a market price of $100.10 per share, or $8.22 per share higher than the conversion price. The value of the beneficial conversion feature was determined by multiplying this difference in the per share price of our common stock by the 326,498 underlying shares. This amount was amortized to interest expense using the effective interest method over the five-year term of the notes, or shorter period in the event of conversion of the 4.50% Notes. Debt discount related to the 4.50% Notes was amortized to interest expense using the effective interest method. There was no remaining amortization of the beneficial conversion feature for the years ended December 31, 2011 and 2010.

Following the closing of the November 15, 2006 sale of $16,500,000 of the 7.00% Notes due September 1, 2011, holders of an aggregate of $27,500,000 of the 4.50% Notes agreed to exchange and redeem their 4.50% Notes for an aggregate of $16,500,000 in aggregate principal amount of the 7.00% Notes and $11,000,000 in cash, plus accrued and unpaid interest on the 4.50% Notes of $254,000. As a result of negotiations between us and the holders of the 4.50% Notes, the $2,500,000 outstanding principal balance related to the 4.50% Notes was not redeemed by us on the original maturity date of September 1, 2008. Interest of $56,000 related to the 4.50% Notes was paid on September 1, 2008. Subsequently on December 11, 2008, the trustee of the Indenture and the holders of the $2,500,000 outstanding principal balance related to the 4.50% Notes agreed to extend the maturity date of the 4.50% Notes to September 1, 2009, and to waive any past default by us of our obligation to make payment on the principal of and interest on the 4.50% Notes. We agreed to extend each holder s rights to require us to repurchase the 4.50% Notes at 105% of such holder s outstanding principal amount upon a change in control, as defined in the indenture governing the 4.50% Notes, and to convert the 4.50% Notes into common stock accordingly. In addition, the holders of the 4.50% Notes agreed to permit the full redemption of the outstanding principal related to the 4.50% Notes at a redemption price of 100% on or before August 31, 2009, and we agreed to adjust the conversion rate for the 4.50% Notes to 20 shares per $1,000 principal amount of the 4.50% Notes, which is equal to a conversion price of $50.00 per share. The impact from adjusting the conversion rate was de minimis.

In November 2009, we exchanged a total of 6,750 shares of common stock for $135,000 in principal and $8,000 in unpaid interest. The conversion rate for redemption was approximately 47 shares per $1,000 principal amount. We recorded an additional debt conversion expense of $69,000 relating to the more favorable exchange rate.

We were in default of the 4.50% Notes as of December 31, 2009. However, upon the emergence from bankruptcy under Chapter 11, we cured the default with a payment of $2,365,000 of principal and $140,000 of unpaid interest with $2,195,000 of cash and 9,044 shares of common stock. This payment settled the 4.50% Notes in full. There was no remaining principal amount of the 4.50% Notes remaining at December 31, 2011 or 2010.

NOTE 9: Commitments and Contingencies

Operating Leases

We lease various equipment and facilities to support our business of discovering, developing and commercializing diagnostic tests in the fields of oncology, cardiology and women s health. On June 1, 2010, we entered into a noncancelable operating lease for a new principal facility located in Austin, Texas in conjunction with our relocation of our corporate headquarters to Austin, Texas. The term was from June 1, 2010 through May 31, 2012, with an annual base rent of $57,000 and annual estimated common area charges, taxes and insurance of $37,000. In March 2012, we amended this lease on the same terms and extended the term to May 31, 2013.

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On June 3, 2008, we entered into a noncancelable operating lease for a new principal facility located in Fremont, California. Under the lease agreement, the term was from July 1, 2008 through June 30, 2010, with an annual base rent of $87,000 and $92,000 for the first year and second year, respectively. We also paid common area charges, taxes and insurance with an annual estimated cost of $21,000. This lease was extended to and expired on August 31, 2010. Additionally, under the lease agreement, we pledged a $100,000 certificate of deposit as collateral on a letter of credit serving as a security deposit for the first year. For the second year, the certificate of deposit pledged as collateral on a letter of credit serving as a security deposit was reduced to $60,000. The letter of credit expired during the year ended December 31, 2010 and the $60,000 security deposit was returned to us.

Rental expense under operating leases for the years ended December 31, 2011 and 2010 totaled $129,000 and $149,000, respectively.

As of December 31, 2011, including the extension of our Austin, TX facility operating lease in March 2012, future minimum rental payments under noncancelable operating leases were $121,000 and $40,000 for the years ending December 31, 2012 and 2013, respectively.

Noncancelable Collaboration Obligations and Other Commitments

Under the terms of a research collaboration agreement with The Johns Hopkins University School of Medicine (JHU) directed at the discovery and validation of biomarkers in human subjects, including but not limited to clinical application of biomarkers in the understanding, diagnosis and management of human diseases, we were required to pay JHU $600,000, $618,000 and $637,000 for the years ending December 31, 2008, 2009 and 2010, respectively. In June 2010, the research collaboration agreement was amended by extending the term and reducing the payments to $300,000 for 2010, $400,000 for 2011, $400,000 for 2012 and $100,000 for 2013. In conjunction with the amendment, JHU forgave the previously outstanding amounts 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 expenses under the JHU collaboration were $235,000 and $400,000 for the years ended December 31, 2011 and 2010, respectively. Collaboration expenses 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 $52,500. As of December 31, 2011 and 2010, we owed $4,000 related to research collaboration agreements with JHU.

Contingent Liabilities

Molecular Analytical Systems, Inc. Litigation

On July 9, 2007, Molecular Analytical Systems (MAS) filed a lawsuit in the Superior Court of California for the County of Santa Clara naming Vermillion and Bio-Rad Laboratories, Inc. (Bio-Rad) as defendants (the State Court lawsuit). In connection with the State Court lawsuit, MAS sought an unspecified amount of damages and alleged, among other things, that we breached our license agreement with MAS relating to SELDI technology by entering into a sublicense agreement with Bio-Rad. We filed our general denial and affirmative defenses on April 1, 2008. The State Court lawsuit was automatically stayed 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 in the Bankruptcy Court on July 15, 2009. The proof of claim mirrored the State Court lawsuit, alleging that we breached our license agreement with MAS 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. After the Plan of Reorganization was confirmed, MAS filed a motion with the Bankruptcy Court requesting that it abstain from hearing its proof of claim and that it grant MAS 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 16, 2010. Thereafter, the Superior Court ordered that the dispute

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be arbitrated before the Judicial Arbitration and Mediation Service. MAS filed its demand for arbitration on September 15, 2010. The demand did not include any additional detail regarding MAS s claims and attached the same complaint for unspecified damages that MAS filed in the Superior Court in 2007. The parties thereafter conducted discovery, and the arbitration hearing commenced on September 21, 2011. Both sides presented evidence over five hearing days ending on October 4, 2011. The parties completed post-hearing briefing on November 9, 2011 and presented closing arguments on November 11, 2011. On February 23, 2012, an interim arbitration award was issued by the Arbitrator. In the interim arbitration award, the Arbitrator denied MAS s claim for breach of the license agreement as well as several other of MAS's claims. The Arbitrator found that MAS was entitled to an accounting concerning our 2% royalty obligation either for 10 years (from February 21, 2003 through February 21, 2013) or until cumulative royalty payments reached $10 million, whichever comes first, and ordered that such royalties should be based on our total GAAP revenues, less revenues attributable to certain excluded entities, not just SELDI-related revenues. The Arbitrator also ordered that the parties meet and confer regarding further proceedings relating to the accounting. We have accrued for the amount deemed estimable and probable of loss, and not previously paid to MAS, pursuant to the interim arbitration award within general and administrative expense at December 31, 2011. The amount was not material to the financial statements for the year ended December 31, 2011. We anticipate receiving a final arbitration award consistent with the interim arbitration award by June 2012 and believe the possibility of any material loss in excess of the amount accrued is remote; however, management cannot predict the content nor control the timing of the final arbitration award at this time.

Bio-Rad Laboratories, Inc. Matters

On November 13, 2006, we sold assets and liabilities of our protein research tools and collaborative services business (the Instrument Business Sale), to Bio-Rad, in order to concentrate our resources on developing clinical protein biomarker diagnostic products and services. The Instrument Business Sale included our 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 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

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October 29, 2008. In October 2009, Bio-Rad filed a proof of claim in our bankruptcy case based on certain contract claims for approximately $1,000,000. We are attempting to resolve the contract claims and have accrued for this contingency within general and administrative expense at December 31, 2011 and 2010. Management cannot predict the ultimate outcome of this matter at this time.

Patrick Gillespie Litigation

On February 28, 2012, Robert Goggin III, a purported shareholder of Vermillion, filed for and obtained a writ of summons in Pennsylvania state court as a precursor to filing a lawsuit against Vermillion. Goggin discontinued his case on February 29, 2012. Thereafter, on March 12, 2012, Patrick Gillespie, a purported shareholder of Vermillion, represented by the same counsel as Goggin, filed for and obtained a writ of summons in Pennsylvania state court as a precursor to filing a lawsuit against Vermillion. On March 22, 2012, Gillespie asked the court to issue letters rogatory to permit pre-suit discovery. We dispute any claims that Gillespie may make and intend to defend this matter vigorously. Due to the fact that complaints have not yet been filed in the proceedings, we cannot estimate its likely impact on us.

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

NOTE 10: COMMON STOCK

Stockholders Rights Plan

We adopted a Stockholder Rights Plan, the purpose of which is, among other things, to enhance our Board of Directors ability to protect stockholder interests and to ensure that stockholders receive fair treatment in the event any coercive takeover attempt of the Company is made in the future. The Stockholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring us or a large block of our common stock. The following summary description of the Stockholder Rights Plan does not purport to be complete.

The rights issued pursuant to Vermillion s Stockholder Rights Plan will become exercisable the tenth day after a person or group announces acquisition of 15.0% 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 15.0% or more of our common stock. If the rights become exercisable, the holders of the rights (other than the person acquiring 15.0% 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.

2010 Private Placement Sale

On January 7, 2010, in connection with the Second Amended Plan of Reorganization under Chapter 11 (Plan of Reorganization), we completed a private placement sale of 2,327,869 shares of our common stock to a group of new and existing investors for $43,050,000 in gross proceeds.

2007 Private Placement Sale

On August 29, 2007 (the Closing Date), we completed a private placement sale of 2,451,309 shares of our common stock and warrants to purchase up to an additional 1,961,047 shares of our common stock with an exercise price of $9.25 per share and expiration date of August 29, 2012, to a group of new and existing investors for $20,591,000 in gross proceeds (collectively referred to as the August 29, 2007, Private Placement Sale). Existing investors included affiliates of the Company, who purchased 964,285 shares of our common stock and

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warrants to purchase up to an additional 771,428 shares of our common stock for $8,100,000. In connection with Quest Diagnostics participation in this transaction, we amended a warrant to purchase an additional 220,000 shares of our common stock that was originally issued to Quest Diagnostics on July 22, 2005. Pursuant to the terms of the amendment, the exercise price for the purchase of our common stock was reduced from $35.00 per share to $25.00 per share and the expiration date of such warrant was extended from July 22, 2010 to July 22, 2011. The warrant expired unexercised in 2011. For services as placement agent, we paid Oppenheimer & Co. Inc. (Oppenheimer) $1,200,000 and issued a warrant to purchase up to 92,100 shares of our common stock with an exercise price of $9.25 per share and expiration date of August 29, 2012. The warrants issued to the investors and Oppenheimer were valued at $7,194,000 and $581,000, respectively, based on the fair value as determined by the Black-Scholes model. The amended value of the warrant issued to Quest Diagnostics on July 22, 2005, increased by $356,000, which is reflected in additional paid-in capital, from its original value of $2,200,000. Assumptions used to value the warrants issued to the investors and Oppenheimer, and the amended value of the warrant issued to Quest Diagnostics were as follows:

	Private Investors and Oppenheimer & Co. Inc.	Amendment to Quest Diagnostics Incorporated
Dividend yield	%	%
Volatility	80.14%	82.92%
Risk-free interest rate	4.31%	4.24%
Expected lives (years)	5.0	3.9

Our outstanding warrants from the August 2007 offering are classified as liabilities in accordance with ASC 815, which requires the warrants to be fair valued at each reporting period, with the changes in fair value recognized as interest and other expense in our consolidated statement of operations.

At December 31, 2011 and 2010, we had warrants outstanding to purchase 195,012 shares of common stock which were required to be classified as a liability. The fair value of these warrants at December 31, 2011 and 2010 was determined using a Black Scholes valuation model with the following level 3 inputs:

	December 31,	
	2011	2010
Risk-free interest rate	0.08%	0.52%
Expected life (in years)	0.66	1.66
Dividend yield	%	%
Volatility	72.16%	64.62%
Stock price	$ 1.17	$ 7.52

For the years ended December 31, 2011 and 2010, we recorded gains of $378,000 and $4,353,000 in the consolidated statements of operations under ASC 815.

Our warrant liability at December 31, 2011 was de minimis. The following table sets forth our financial liabilities related to warrants subject to fair value measurements as of December 31, 2010:

		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 at December 31, 2010 Common stock warrants	$ 378	$	$	$ 378
Total	$ 378	$	$	$ 378

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The following table is a reconciliation of the warrant liability measured at fair value using Level 3 inputs:

(in thousands)	Year Ended December 31, 2011	2010
Balance at beginning of period	$ 378	$ 5,659
Change in fair value of common stock warrants	(378)	(4,132)
Warrant exercise gain		(223)
Reclassification of warrant fair value to equity upon exercise and issuance of common stock		(926)
Balance at end of period	$	$ 378

Warrants

Warrants outstanding as of December 31, 2011 and 2010 were as follows:

Issuance Date	Expiration Date	Exercise Price per Share	Number of Shares Outstanding under Warrant December 31, 2011	December 31, 2010
July 22, 2005	July 22, 2011	$ 25.00		220,000
August 3, 2006	August 3, 2011	12.60		385
November 15, 2006	November 15, 2011	12.60		385
August 29, 2007	August 29, 2012	9.25*	195,012	195,012
November 1, 2011	October 31, 2013	3.23	21,000	
			216,012	415,782

* The exercise price of the warrants issued on August 29, 2007 is adjustable in accordance with the term of the warrants.

On November 1, 2011, we issued warrants to purchase up to 21,000 shares of our common stock with an exercise price of $3.23 per share and an expiration date and an expiration date of October 31, 2013 to a vendor in exchange for services. The warrants vest pro-rata on a monthly basis over a six month period. The value of the warrants as determined by the Black-Sholes model was not significant and is classified as equity.

Debtor s Incentive Plan

In connection with the Bankruptcy Filing, on April 21, 2009, we filed the Debtor's Motion for Entry of an Order Approving the Debtor s Incentive Plan (the Debtor s 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 sale or restructuring of the Company. At a hearing on June 22, 2009, the Court entered an Order approving the Incentive Plan Motion (the Incentive Plan Order). The Debtor s Incentive Plan is only triggered upon the occurrence of a qualified transaction defined as the closing of any sale pursuant to section 363 of the Bankruptcy Code or the effectiveness of a Reorganization Plan confirmed pursuant to section 1129 of the Bankruptcy Code. The Debtor s Incentive Plan payment was based upon a percentage of (A) the gross proceeds of Asset Sales, both prior to and after the Food and Drug Administration approval of the ovarian tumor triage test, and (B) the value of consideration cash, debt and equity - distributed pursuant to a confirmed Reorganization Plan. In the end, the Incentive Plan Order provided that the Directors would receive: (i) zero, on Qualified Transaction Proceeds of 3,000,000 or less, (ii) 6% on Qualified Transaction Proceeds of $3,000,001 to $10,000,000, and (iii) 8% on Qualified Transaction Proceeds of greater than $10,000,000. While the Incentive Plan Order provided us with the authority to make distributions under the Debtor s Incentive Plan, we agreed as part of the Plan of Reorganization to seek final judicial approval of the amounts to be paid pursuant to the Debtor s Incentive Plan. On April 13, 2010, our counsel, the Official Committee of the Equity Security

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Holders, and the Directors submitted a proposed settlement to the Bankruptcy Court. On April 14, 2010, after a hearing, an order was issued by the Bankruptcy Court approving the Debtor s Incentive Plan. Under the Debtor s Incentive Plan, we were 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 Debtor s Incentive Plan payments to the Directors. All such restricted stock vests with respect to 1/24th of the total distributed on each monthly anniversary of the vesting commencement date, June 22, 2009. The total Debtor s Incentive Plan payments were allocated to Gail Page, James Burns and John Hamilton on a 60%-20%-20% basis, respectively. The contingency was accounted for upon the occurrence of the qualified transaction on January 7, 2010 when the Bankruptcy Courts issued a confirmation order approving our Reorganization Plan. For the year ended December 31, 2011, we incurred $1,657,000 under the terms of the Debtor s Incentive Plan recorded in general and administrative expenses. For the year ended December 31, 2010, we incurred $9,969,000 under the terms of the Debtor s Incentive Plan, of which $6,932,000 was recorded in Reorganization Items for the period prior to emerging from bankruptcy under Chapter 11 and $3,037,000 was recorded in general and administrative expenses for the period subsequent to emerging from bankruptcy under Chapter 11. In April 2010, we distributed an aggregate of $5,000,000 in cash to the Directors. We distributed 75,637 and 226,904 shares of common stock to the Directors under the Debtor s Incentive Plan during the year ended December 31, 2011 and 2010, respectively.

NOTE 11: Accumulated Other Comprehensive Loss

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

(In thousands)	Year Ended December 31, 2011	2010
Cumulative translation adjustment	(153)	(156)
Accumulated other comprehensive loss	$ (153)	$ (156)

NOTE 12: Loss Per Share

The reconciliation of the numerators and denominators of basic and diluted loss per share for the years ended December 31, 2011 and 2010 was as follows:

(In thousands, except per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
Year ended December 31, 2010:			
Net loss basic	$ (19,034)	10,404,741	$ (1.83)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, conversion of convertible senior notes and unvested restricted stock awards			
Net loss diluted	$ (19,034)	10,404,741	$ (1.83)
Year ended December 31, 2011:			
Net loss basic	$ (17,790)	14,249,570	$ (1.25)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards			
Net loss diluted	$ (17,790)	14,249,570	$ (1.25)

Due to net losses for the years ended December 31, 2011 and 2010, diluted loss per share is calculated using the weighted average number of common shares outstanding and excludes the effects of potential common stock

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shares that are antidilutive. The potential shares of common stock that have been excluded from the diluted loss per share calculation above for the years ended December 31, 2011 and 2010 were as follows:

	Year Ended December 31,	
	2011	2010
Stock options	930,060	849,485
Stock warrants	216,012	415,782
Convertible senior notes		250,000
Restricted stock units	114,748	81,889
Potential common shares	1,260,820	1,597,156

NOTE 13: EMPLOYEE BENEFIT PLANS

1993 Stock Option Plan

We have no shares of our common stock reserved for future grants to employees, directors or consultants under our 1993 Stock Option Plan (the 1993 Plan). Under the 1993 Plan, options were granted at prices not lower than 85% and 100% of the fair market value of the common stock for non-statutory and statutory stock options, respectively. All outstanding options under the 1993 Plan are now fully vested, and unexercised options generally expire ten years from the date of grant. The authority of our Board of Directors to grant new stock options and awards under the 1993 Plan terminated in 2001. At December 31, 2011 and 2010, no shares of our common stock were subject to repurchase by us. There were no 1993 Plan option exercises for the years ended December 31, 2011 and 2010. There are no shares of stock options that remain outstanding under the 1993 Plan.

2000 Stock Plan

Under the Amended and Restated 2000 Stock Plan (the 2000 Plan), options may be granted at prices not lower than 85% and 100% of the fair market value of the common stock for non-statutory and statutory stock options, respectively. Options generally vest monthly over a period of four years and unexercised options generally expire ten years from the date of grant. The authority of our Board of Directors to grant new stock options and awards under the 2000 Plan terminated in 2010. Options to purchase 21,833 and 21,083 shares of common stock were exercised during the years ended December 31, 2011 and 2010, respectively. As of December 31, 2011, options to purchase 596,047 shares of common stock remained outstanding under the 2000 Plan. No additional shares of our common stock were reserved for future option grants under the 2000 Plan.

2000 Employee Stock Purchase Plan

The Amended and Restated 2000 Employee Stock Purchase Plan (the 2000 ESPP) provides for eligible employees to purchase our common stock through payroll deductions during six-month offering periods. Each offering period begins on May 1 or November 1 and ends October 31 or April 30, respectively.

The 2000 ESPP provides for the purchase of our common stock at the lower of 85.00% of the closing price of our common stock on the first day of the offering period or 85.00% of the closing price of our common stock on the last day of the offering period. No additional common stock shares were reserved for issuance under the 2000 ESPP for the years ended December 31, 2011 and 2010.

2010 Stock Incentive Plan

On February 8, 2010, our Board of Directors approved the Vermillion, Inc. 2010 Stock Incentive Plan (the 2010 Plan). The 2010 Plan is administered by the Compensation Committee of the Board of Directors. Our 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

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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. Unexercised options generally expire ten years from the date of grant. There were no 2010 Plan option exercises for the years ended December 31, 2011 and 2010.

During the year ended December 31, 2011, we awarded 177,000 shares of restricted stock from the 2010 Plan having a fair value of $724,000 to our executive officers. All such restricted stock vests ratably on a quarterly basis over a three year period beginning on the vesting commencement in March 2011. We distributed 42,250 of these shares of common stock to our officers during the year ended December 31, 2011.

On September 29, 2011, our Board of Directors approved the Company making income tax gross-up payments to our Chief Executive Officer in connection with the distribution of the 85,000 shares of restricted stock granted on March 18, 2011. A letter agreement to this effect was executed on October 3, 2011. We expensed approximately $22,000 related to this letter agreement during the year ended December 31, 2011. A total of 21,250 of the 85,000 common shares have been distributed through December 31, 2011.

During the year ended December 31, 2010, we awarded 25,000 shares of restricted stock from the 2010 Plan having a fair value of $146,000 to employees in connection with our emergence from bankruptcy. All such restricted stock vests with respect to 1/24th of the total distributed on each monthly anniversary of the vesting commencement on June 22, 2009. We distributed 6,252 and 18,748 of these shares of common stock to employees during the years ended December 31, 2011 and 2010, respectively.

During the year ended December 31, 2011, we issued 97,295 shares of restricted stock from the 2010 Plan having a fair value of $373,000 to the Board of Directors as payment for services rendered in 2011. During the year ended December 31, 2010, we issued 81,000 shares of restricted stock from the 2010 Plan having a fair value of $426,000 to the Board of Directors as payment for services rendered in 2010.

The activity related to shares available for grant under the 1993 Plan, 2000 Plan, 2000 ESPP and 2010 Plan for the years ended December 31, 2011 and 2010 were as follows:

	1993 Stock Option Plan	2000 Stock Plan	2000 Employee Stock Purchase Plan	2010 Stock Option Plan	Total
Shares available at December 31, 2009		6,553,859	1,369,273		7,923,132
Additional shares reserved				1,322,983	1,322,983
Options canceled	1,720	9,013		500	11,233
Reduction in shares reserved	(1,720)				(1,720)
Options granted				(203,500)	(203,500)
Restricted stock units granted				(106,000)	(106,000)
Shares expired		(6,562,872)	(1,369,273)		(7,932,145)
Shares available at December 31, 2010				1,013,983	1,013,983
Options canceled		28,605		60,917	89,522
Reduction in shares reserved		(28,605)			(28,605)
Options granted				(191,930)	(191,930)
Restricted stock units canceled				20,000	20,000
Restricted stock units granted				(274,295)	(274,295)
Shares expired					
Shares available at December 31, 2011				628,675	628,675

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The stock option activity under the 1993 Plan, 2000 Plan and 2010 Plan for the years ended December 31, 2011 and 2010 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Options outstanding at December 31, 2009	678,301	$ 14.22	$ 12,648	5.86
Granted	203,500	20.93		
Exercised	(21,083)	1.99		
Canceled	(11,233)	14.76		
Options outstanding at December 31, 2010	849,485	$ 16.13	$ 1,924	5.81
Granted	191,930	2.40		
Exercised	(21,833)	1.55		
Canceled	(89,522)	23.04		
Options outstanding at December 31, 2011	930,060	$ 12.97	$ 16	5.90
Shares exercisable:				
December 31, 2011	644,688	$ 15.48	$ 16	4.46
Shares expected to vest:				
December 31, 2011	170,052	$ 7.30	$	9.04

The range of exercise prices for options outstanding and exercisable at December 31, 2011 are as follows:

Exercise Price		Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Options Exercisable	Weighted Average Exercise Price
$0.01	$0.75	37,499	$ 0.75	2.43	37,499	$ 0.75
0.76	2.04	255,250	1.99	7.26	100,861	2.04
2.05	2.30	175,209	2.30	6.54	148,955	2.30
2.31	5.52	62,013	4.93	8.91	14,363	5.07
5.53	10.20	78,748	9.33	2.86	77,133	9.32
10.21	14.70	122,548	13.29	4.77	115,650	13.40
14.71	29.60	146,998	26.85	6.53	98,432	25.97
29.61	96.00	51,795	87.05	1.38	51,795	87.05
$0.01	$96.00	930,060	$ 12.97	5.90	644,688	$ 15.48

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2011	$ 52	$ 1,218
Year ended December 31, 2010	$ 183	$ 1,124

Stock-Based Compensation

Employee Stock-based Compensation Expense

The assumptions used to calculate the fair value of options granted under the 2010 Plan that were incorporated in the Black-Scholes pricing model for the years ended December 31, 2011 and 2010 were as follows:

	Year Ended December 31,	
	2011	2010
Dividend yield	%	%
Volatility	77%	81%
Risk-free interest rate	1.28%	2.25%
Expected lives (years)	5.7	5.6
Weighted average grant-date fair value	$ 1.60	$ 14.49

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The allocation of stock-based compensation expense by functional area for the years ended December 31, 2011 and 2010 was as follows:

(in thousands)	Year Ended December 31, 2011	2010
Research and development	$ 683	$ 954
Sales and marketing	158	72
General and administrative	2,442	3,768
Total	$ 3,283	$ 4,794

We have a 100.0% valuation allowance recorded against our deferred tax assets, and as a result ASC 718 had no effect on income tax expense in the consolidated statement of operations or the consolidated statement of cash flows. As of December 31, 2011, total unrecognized compensation cost related to nonvested stock option awards was $461,000 and the related weighted average period over which it is expected to be recognized was 2.63 years.

Non-employee Stock-based Compensation Expense

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. Certain former employees were converted into consultants to the Company whereby their existing stock options continued to vest, under the original terms of their stock option grants, as they provided consulting services to us. The values attributable to these options are amortized over the service period and the unvested portion of these options was remeasured 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. The fair value of the stock options granted were revalued at each reporting date using the Black-Scholes valuation model as prescribed by ASC 505, Equity, using the following average assumptions:

	Year Ended December 31, 2011	2010
Dividend yield	%	%
Volatility	80%	82%
Risk-free interest rate	1.07%	3.19%
Expected lives (years)	5.66	7.81
Weighted average fair value	$ 1.07	$ 14.44

The stock-based compensation expense will fluctuate as the fair market value of the common stock fluctuates. In connection with stock options relating to non-employees, we recorded stock-based compensation allocated by functional area for the years ended December 31, 2011 and 2010 as follows:

(in thousands)	Year Ended December 31, 2011	2010
Research and development	$ 3	$ 38
Sales and marketing		5
General and administrative	4	100
Total	$ 7	$ 143

401(k)Plan

Our 401(k) Plan allows eligible employees to defer up to an annual limit of the lesser of 90.0% of eligible compensation or a maximum contribution amount subject to the Internal Revenue Service annual contribution limit. We are not required to make contributions under the 401(k) Plan. As of December 31, 2011 and 2010, we have not contributed to the 401(k) Plan.

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NOTE 14: INCOME TAXES

Domestic and foreign components of loss before income taxes for the years ended December 31, 2011 and 2010 were as follows:

(in thousands)	Year Ended December 31, 2011	2010
Domestic	$ (17,696)	$ (18,907)
Foreign	(94)	(127)
	$ (17,790)	$ (19,034)

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, we have provided a full valuation allowance against our net deferred tax assets at December 31, 2011 and 2010. There was no income tax expense or benefit for the years ended December 31, 2011 or 2010.

The components of deferred tax assets (liabilities) at December 31, 2011 and 2010 were as follows:

(in thousands)	Year Ended December 31, 2011	2010
Deferred tax assets:		
Depreciation and amortization	$ 11,158	$ 14,068
Other	1,617	1,606
Net operating losses	42,443	41,789
Total deferred tax assets	55,218	57,463
Valuation allowance	(55,210)	(57,433)
Net deferred tax assets	$ 8	$ 30
Deferred tax liabilities:		
Other	$ (8)	$ (30)
Total deferred tax liabilities	$ (8)	$ (30)
Net deferred tax asset (liabilitiy)	$	$

The reconciliation of the statutory federal income tax rate to the Company s effective tax rate for the years ended December 31, 2011 and 2010 was as follows:

	Year Ended December 31, 2011	2010
Tax at federal statutory rate	34%	34%
State tax, net of federal benefit	2	7
Valuation allowance	(17)	(14)
Change in warrant valuation	1	8
Net operating loss and credit reduction due to section 382 limitations	(11)	(32)
Permanent items	(9)	(4)
Other		1

Effective income tax rate	%	%

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As of December 31, 2011, we had a net operating loss of approximately $114,000,000 for federal and $87,000,000 for state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2017 for federal and 2012 for state purposes. In 2012, approximately $2,100,000 of state net operating loss will expire and the state net operating losses will continue to expire in 2013. If not utilized, the remaining federal net operating loss will begin to expire in 2017, and the state net operating loss will continue to expire in 2013. As of December 31, 2010, we had a net operating loss of approximately $103,000,000 for federal and $75,000,000 for state tax purposes.

Our ability to use our net operating loss 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 (Section 382), as amended, as well as similar state provisions. These ownership changes may also limit the amount of net operating loss credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

We believe that a Section 382 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 net operating loss credit carryforwards before utilization and any net operating loss 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.

As of December 31, 2011 and 2010, we had $6,300,000 and $6,100,000 of net operating loss carryforwards from our Japan operations, respectively. If not utilized, this carryforward will begin to expire in 2012.

We believe that it is more likely than not that the benefit from certain deferred tax assets will not be realized due to the history of our operating losses. In recognition of this risk, we have provided a valuation allowance on the deferred tax assets relating to these assets. The valuation allowance was $55,210,000 and $57,433,000 at December 31, 2011 and 2010, respectively. The decrease of $2,223,000 between 2011 and 2010 is primarily due to adjustments to the domestic deferred tax assets, including a decrease in the effective state tax rate.

We file income tax returns in the U.S. and in various state jurisdictions with varying statutes of limitations. We have not been audited by the Internal Revenue Service or any state income or franchise tax agency. As of December 31, 2011, our federal returns for the years ended 2008 through the current period and most state returns for the years ended 2007 through the current period are still open to examination. In addition, all of the net operating losses and research and development credits generated in years earlier than 2008 and 2007, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2010 reflect research and development carryforwards of $545,000 and $5,089,000, respectively. We have recognized additional deferred tax assets for federal and California research and development credits of $136,000 and $102,000 for the year ended December 31, 2011, respectively. As of December 31, 2011, our gross unrecognized tax benefits are approximately $5,872,000 which are attributable to research and development credits. A reconciliation of the change in our unrecognized tax benefits is as follows:

(in thousands)	Federal Tax	State Tax	Total
Balance at December 31, 2009	$	$	$
Increase in tax position during 2010	545	5,089	5,634
Balance at December 31, 2010	$ 545	$ 5,089	$ 5,634
Increase in tax position during 2011	136	102	238
Balance at December 31, 2011	$ 681	$ 5,191	$ 5,872

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The increase for the year ended December 31, 2011 relates to a tax position taken during 2011. The increase for the year ended December 31, 2010 is related to tax positions taken during 2010 and prior years. If the $5,900,000 of unrecognized income tax benefit is recognized, approximately $5,900,000 would impact the effective tax rate in the period in which each of the benefits is recognized.

We do not expect our unrecognized tax benefits to change significantly over the next 12 months. We recognize interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations. We have not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2011 and 2010. Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

NOTE 15: OTHER RELATED PARTY TRANSACTIONS

Consulting Agreements

On March 26, 2009, we entered into a consulting agreement with our former chief executive officer and current Director. For the years ended December 31, 2011 and 2010, we incurred none and $24,000 in general and administrative expenses under the consultant arrangement, respectively. On February 1, 2010, we re-hired the consultant as our chief executive officer.

On September 14, 2009, we entered into a consulting agreement with our former Vice President and Chief Science Officer, Eric T. Fung, M.D., Ph.D. For the year ended December 31, 2010, we incurred $48,000 in research and development expenses under the consulting arrangement. On February 1, 2010, this consulting agreement was terminated when we re-hired Dr. Fung as our Senior Vice President and Chief Science Officer. On November 2, 2011, we again entered into a consulting agreement with Dr. Fung, who resigned effective on November 4, 2011. Pursuant to the terms of the consulting agreement, Dr. Fung will serve as our Chief Medical Officer and a member of our Scientific Advisory Board. For the year ended December 31, 2011, the total amount of consulting fee expense for Dr. Fung was $6,000.

On June 17, 2011, we entered into a consulting agreement with Bruce A. Huebner. Pursuant to the terms of the consulting agreement, Mr. Huebner provides consulting services regarding sales, marketing, business development and corporate strategy. For the year ended December 31, 2011, the total amount of consulting fee expense for Mr. Huebner was $9,200.

On March 1, 2012, we entered into a consulting agreement with our former Vice President of Strategy, who resigned effective February 29, 2012. Pursuant to the terms of the consulting agreement, our former Vice President of Strategy will provide consulting services.

NOTE 16: SUBSEQUENT EVENTS

In January 2012, we announced a restructuring plan to streamline our organization and reduce our cash expenditures compared to 2011. This plan included eliminating the positions of Chief Financial Officer and Vice President of Corporate Strategy as well as a reduction in our Territory Development and sales management personnel.

On February 9, 2012, we entered into a Settlement Agreement and Release (the Settlement Agreement) with a third party related to losses on our short and long-term investments in previous years. Under the terms of the Settlement Agreement, we will receive a total settlement of $1,000,000 (the Total Settlement Amount); $535,000 was paid in March 2012 and $465,000 is payable by September 1, 2012. We expect to receive approximately 70% of the Total Settlement Amount, net of legal and related costs, and will record the net amount in other income when realized.

On March 22, 2012, we granted approximately 264,000 stock options to our executive officers and employees, vesting monthly over a three year period. In addition, we granted approximately 191,000 stock options to our executive officers and employees vesting 100% at March 31, 2013.