

VERMILLION, INC.  
Form 10-K  
March 01, 2013  
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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, 2012.**

.. **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**  
(State or other jurisdiction of  
  
incorporation or organization)

**33-0595156**  
(I.R.S. Employer  
  
Identification No.)

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12117 Bee Caves Road, Building Three,

Suite 100, Austin, Texas  
(Address of principal executive offices)

78738  
(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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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.

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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-Accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>

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

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  No

The aggregate market value of voting common stock held by non-affiliates of the Registrant is \$30,444,327 and is based upon the last sales price as quoted on The NASDAQ Global Market as of June 30, 2012.

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As of February 28, 2013, the Registrant had 15,200,079 shares of common stock, par value \$0.001 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

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<p><i>Vermillion, OVA1, VASCLR and OvaCalc</i> are registered trademarks of Vermillion, Inc. <i>ProteinChip</i> is a registered trademark of Bio-Rad Laboratories, Inc. <i>BioSeptra</i> is a registered trademark of Pall Corporation.</p>	

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**PART I**

**FORWARD-LOOKING STATEMENTS**

Vermillion, Inc. ( Vermillion ) and its 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, expect, intend, anticipate, believe, estimate, plan, could, should, 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 particular 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 ) or elsewhere;

our ability to expand and protect our intellectual property portfolio;

anticipated future losses;

expected levels of expenditures;

expected market adoption of our diagnostic tests, including OVA1;

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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;

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

expected reimbursement for our products from third party payers such as private insurance companies and government insurance plans.

Such statements are subject to significant risks and uncertainties, including those identified in Part 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; 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

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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**

##### Corporate Vision:

To become a recognized leader in the advancement of women's health by providing innovative methods to detect, monitor and manage the treatment of gynecologic cancers and other related diseases

##### Corporate Mission:

We will develop and commercialize high-value multi-marker diagnostic tests which address unmet needs in gynecologic oncology and women's health.

We will accomplish our mission through internal development, targeted acquisitions, and collaborations with leading scientific and clinical institutions.

Our commercial efforts will include direct marketing and sales activities as well as partnerships with leading companies in women's health.

##### Mission Statement:

We are dedicated to the discovery, development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Our tests are intended to detect, diagnose and stage disease, and to help guide decisions regarding patient prognosis and treatment. These may include decisions to refer patients to specialists, to perform additional testing, or to assist in the selection or monitoring of therapy and disease progression. A distinctive feature of our approach is to combine multiple biomarkers into a single, reportable index score that has higher diagnostic effectiveness than its constituents. We concentrate our development of novel diagnostic tests in the fields of gynecologic oncology and women's health, with the initial focus on ovarian cancer. We also intend to address clinical unmet needs related to early disease detection, treatment response, monitoring of disease progression, prognosis and others through collaborations with leading academic and clinical research institutions.

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



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In 2012, we completed a second pivotal clinical study of OVA1, called the OVA500 study and led by Dr. Robert E. Bristow, Director of Gynecologic Oncology Services with UC Irvine Healthcare. The study evaluated OVA1 performance in a population of 494 patients who underwent surgery for an adnexal mass after enrollment by a non-gynecologic oncologist, the intended use population for routine OVA1 testing. In the new study, of the 27 sites used in each study, only 10 were common to both. Collectively, the two studies evaluated 1,110 eligible subjects at a total of 44 sites. Despite the difference in population between the two studies, and the large number of differing sites, the sensitivity of OVA1 added to clinical impression (also called OVA1 dual assessment) was identical, at 95.7% (88/92). In addition, overall NPV of OVA1 dual assessment was 98.1% (204/208), higher than the 94.6% NPV found in the earlier validation study. In premenopausal surgery patients, OVA1 dual assessment sensitivity was 93.5% (29/31), NPV was 98.6% (145/147) and specificity was 58.9% (145/246) when combined with clinical assessment. OVA1 also showed strong performance in detecting early stage malignancies. OVA1 correctly stratified 91.4% (32/35) of early stage cancers and 89.3% (25/28) of stage I cancers as high risk, respectively. In comparison, CA125-II sensitivity was 65.7% (23/35) for early stage and 64.3% (18/28) for stage I malignancies. Overall, the results strongly and independently confirmed the clinical performance of OVA1 in presurgical triage of adnexal mass patients, including premenopausal and early stage cancers.

The OVA500 study was recently published in the peer-reviewed journal *Gynecologic Oncology*, which enjoys the highest impact factor rating of any journal worldwide focused on gynecologic oncology. The results have also been incorporated into an updated Medical Education presentation, as well as our Marketing and Reimbursement collateral. Since many professional medical societies stress the importance of multiple independent clinical trials as so-called evidence levels, we also believe that OVA500 contributes to a higher evidence level relative to OVA1's utility in the medical management of adnexal masses.

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

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

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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 in the clinical laboratory market until September 2014, with an option to extend such exclusive period in its sole discretion for one additional year. Prior to the expiration of the strategic alliance in October 2012, Quest Diagnostics selected two diagnostic tests to commercialize, a peripheral arterial disease blood test and OVA1.

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.

In November 2011, we entered into an asset purchase agreement with Correlologic Systems, Inc. (**Correlologic**), pursuant to which we paid to Correlologic \$435,000 and purchased from Correlologic substantially all of its assets, including certain documents, diagnostic samples and intellectual property owned by Correlologic in connection with Correlologic's ovarian cancer diagnostics business, including a diagnostic test under the name **OvaCheck2** for the detection of ovarian cancer (the **Acquisition**). Correlologic 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. Court approval was received and the Acquisition completed in December 2011. We plan to use the Correlologic assets purchased from the Acquisition to advance the goals of our ovarian cancer franchise, including the development of the next generation OVA product.

### **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 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 biomarkers enables us to address the market for novel diagnostic tests that simultaneously measure multiple biomarkers. A biomarker is a biomolecule or variant biomolecule that is present

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at measurably 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 biomarker when multiple 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. Such assays are commonly referred to as IVDMA (In Vitro Diagnostic Multivariate Index Assays), and often utilize advanced algorithms based on logistic regression, pattern recognition and the like. Often, IVDMA algorithms are non-intuitive, and therefore require rigorous clinical validation and error modeling. Vermillion and its collaborators are expert in these areas, and in the case of OVA1, presented both the clinical validation and error modeling in order to gain 510(k) clearance of OVA1, as an IVD software device.

### ***Ovarian Cancer***

**Background.** Commonly known as the silent killer, ovarian cancer leads to approximately 15,000 deaths each year in the United States. The American Cancer Society (ACS) estimates that over 22,000 new ovarian cancer cases will be diagnosed in 2013, 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 ACS, 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 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, 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 more than 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 for 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.

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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 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

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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.

In 2012, we completed a second pivotal clinical study of OVA1, called the OVA500 study and led by Dr. Robert E. Bristow, Director of Gynecologic Oncology Services with UC Irvine Healthcare. The study evaluated OVA1 diagnostic performance in a population of 494 evaluable patients who underwent surgery for an adnexal mass after enrollment by a non-gynecologic oncologist. Like the earlier OVA1 validation study, this was a prospective, multi-center study of consecutively enrolled, eligible subjects coordinated through 27 sites across the U.S.A. In the OVA500 study, adnexal surgery patients were only enrolled from non-gynecologic oncology caregivers. As a result, the patient population in this study more closely resembled the intended use population for routine OVA1 testing; women aged 18 years or older, with an adnexal mass requiring surgery but not yet referred to gynecologic oncologist, and in which the mass was determined to be benign or malignant after enrollment. Moreover, of the 27 sites used in each study, only 10 were common to both. So collectively, the two studies evaluated 1,024 eligible subjects at a total of 44 sites. Despite the difference in population between the two studies, and the large number of differing sites, the sensitivity of OVA1 added to clinical impression (also called OVA1 dual assessment) was identical, at 95.7% (88/92). Interestingly, the overall prevalence of malignancy was lower in the OVA500 study than the 31.2% (161/516) previously found in the earlier OVA1 validation study. Cancer prevalence in OVA500 was 18.6% overall (92/494) and just 11.2% (31/277) in premenopausal surgery patients. This difference may be explained by the exclusion of subjects enrolled by gynecologic oncologist, a potentially malignancy-enriched subset of all adnexal mass surgeries. Even so, OVA1 sensitivity was 93.5% (29/31) in premenopausal subjects, with or without clinical assessment. NPV is another critical element of OVA1 performance in the context of a referral or triage test. In OVA500, overall NPV of OVA1 dual assessment was 98.1% (204/208), higher than the 94.6% NPV found in the earlier validation study. In premenopausal subjects, where functional ovarian cysts are more common and gynecologists may elect to operate more frequently, the NPV of OVA1 with or without clinical assessment was 98.6%. In contrast, clinical assessment predicted just 73.9% of malignancies overall, and only 64.5% of premenopausal malignancies. Together, the differential sensitivity and high NPV of OVA1 strongly confirmed previous findings, supporting the evidence of clinical utility in the presurgical triage of patients undergoing adnexal mass surgery. One additional finding related to medical necessity was the detection of early stage malignancies, since stage I cancers are 90-95% curable if appropriately operated and treated. Of the 92 malignancies in OVA500, 35 were early stage and 28 were stage I: 38.0% and 30.4% of all malignancies, respectively. OVA1 standalone sensitivity in stratifying patients as high-risk was 91.4% (32/35) for all early stage and 89.3% (25/28) for stage I malignancies, respectively. Comparatively, CA125-II sensitivity was 65.7% (23/35) for all early stage and 64.3% (18/28) for stage I malignancies. The success rate of OVA1 classifying a benign mass as low risk, although of secondary importance (considering surgery will be performed regardless), was also measured in the OVA500 study. This statistic (specificity) was 53.5% (215/402) overall, and in premenopausal patients was 61.4% (151/246). Overall, the results strongly and independently confirmed the value of OVA1 in presurgical triage of adnexal mass patients, and sensitive identification of premenopausal and early stage malignancies.

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The OVA500 study was recently published in the peer-reviewed journal *Gynecologic Oncology*, which enjoys the highest impact factor rating of any journal worldwide focused on gynecologic oncology. The results have also been incorporated into an updated Medical Education presentation, as well as our Marketing and Reimbursement collateral. Since many professional medical societies stress the importance of multiple independent clinical trials as so-called "evidence levels", we also believe that OVA500 contributes to a higher evidence level relative to OVA1's utility in the medical management of adnexal masses. 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 have shown that the ABI is often performed incorrectly. Recently, a bedside instrument has been introduced to simplify PAD testing, in which blood pressure measurement and user operation have been greatly simplified. The system, called Unetixs REVO, eliminates pre-test resting and takes less than 10 minutes to produce a result. However, the instrument retails for over \$12,000 and uses Pulse Volume waveforms, rather than Doppler waveforms, and requires technician training and accurate placement of pressure cuffs. Our PAD experts advise us that this method has had little uptake and does not produce a validated ABI score. Therefore, a blood test that can be more routinely implemented and reliably drawn by primary care providers has potential in identifying at increased risk of PAD, for referral to vascular medicine specialists.

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 test for identification and specialist referral of patients at higher risk for PAD, similar to the use of OVA1 to detect and refer patients at higher risk of ovarian malignancy.

The results of these early 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.

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The PAD intended use study, titled "A validated biomarker panel to identify peripheral artery disease," and published in the December 2012 edition of *Vascular Medicine*, was authored by Dr. William Hiatt, Novartis Foundation endowed professor for cardiovascular research at the University of Colorado School of Medicine, Division of Cardiology. The article reported the results of a multi-center, prospective clinical study of 1,025 subjects, consecutively enrolled from the PAD at-risk population of those aged 70 or older, and diabetics and smokers 50 or older. Several different multi-marker algorithms were evaluated in at-risk patients with or without PAD, and compared to conventional cardiovascular risk assessment by the Framingham Risk Score (FRS). The best model demonstrated a c-statistic of 0.73 and more important, identified 17 of 20 (85%) of patients with PAD who were missed by the FRS high-risk cutoff. Similar results were seen in asymptomatic PAD subjects, where the algorithm correctly classified 84% (48/57). In a statement, the study's co-author Dr. Cooke commented, "Since one in every 20 Americans over the age of 50 has PAD, this study suggests the possibility for a simple and practical way to screen at-risk patients. By detecting undiagnosed or asymptomatic PAD, primary care physicians can intervene earlier and improve the health and prognosis for their patients. We are truly excited at the confirmation our biomarker research achieved in this large group of at-risk subjects, and look forward to advancing our program."

### **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 had the right to commercialize up to three diagnostic tests from our product pipeline. Prior to the expiration of the strategic alliance, Quest Diagnostics selected two tests, peripheral arterial disease blood test and OVA1. We believe Quest Diagnostics no longer has the right to select the final diagnostic test. Pursuant to the Amended Strategic Alliance Agreement, Quest Diagnostics will have the non-exclusive right to commercialize each of the tests other than OVA1 in the clinical reference laboratory marketplace 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 the clinical reference laboratory marketplace 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. In 2013, we plan to begin a direct selling effort to hospitals which have the required instrumentation and testing capabilities to perform the 5 markers that are in the OVA1 product and utilize the OvaCalc<sup>®</sup> algorithm. Outside the United

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States, laboratories may become customers, either directly with us or via distribution relationships established between us and authorized distributors. In 2013 we plan to begin to actively seek out distributors/partners for the European marketplace.

### **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. In addition, we actively seek collaborations and initiate dialog with clinical academics, in order to generate publications, intellectual property or test development in broader areas of gynecologic oncology.

### **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



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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.

### ***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 and their variants, for example, post-translational modifications, we believe we can improve sensitivity and specificity over traditional diagnostic biomarkers because these biomarker combinations reflect both the pathophysiology and host response. This is accomplished using novel biomarker panels coupled with multivariate pattern recognition software to identify IVDMA algorithms which can be commercialized as disease-specific assays.

We are applying translational biomarker research, algorithm development tools, and statistical error modeling methods to discover robust associations between biomarker panels and clinically relevant disease endpoints. We plan to develop new IVDMA algorithms and molecular diagnostic tests based on known and newly identified protein markers to help physicians better predict and manage disease and treatment, and thereby improve patient outcomes and overall health economic resource utilization. Examples of diagnostic applications include, but are not limited to: asymptomatic population screening, early detection, triage to specialists, aid in diagnosis, prognosis or disease sub-classification, prediction or selection of therapy, monitoring of therapeutic response or residual disease, monitoring for recurrence or identification of appropriate fallback therapy or clinical trial eligibility.

We therefore anticipate ongoing and new partnerships with leading scientific and clinical institutions who have active proteomic or genomic programs in the area of gynecologic cancers, or with relevant clinical trial interests, with the goal of expanding our product portfolio with relevant solutions to unmet medical needs in women's health.

### ***Addressing the Heterogeneity of Disease***

Our strategy is to create a diagnostics paradigm that is based on risk estimation, multiple-biomarker testing and information integration. This strategy is based on the belief that cancer and other gynecologic diseases are heterogeneous and, therefore, that 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 individual 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,

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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, 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 completed a prospective intended use study for PAD in 2011. These activities are outlined below.

***R&D-sponsored initiatives to support market development of 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. The study, called OVA500, has resulted in first publication in the February 2013 edition of *Gynecologic Oncology*, a peer-reviewed journal with the highest impact factor rating of any journal worldwide focused on gynecologic oncology. OVA500 was conducted to confirm and extend the landmark findings of Ueland and Miller, published in *Obstetrics & Gynecology* in the June 2011 edition, with a completely new, prospectively enrolled patient cohort. The findings of OVA500, reported in *Gynecologic Oncology*, are summarized in a preceding section of this document. Additional manuscripts are in preparation to follow up on the initial study report, and will be submitted in the first or second quarter of 2013. The second R&D initiative supporting OVA1 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. While agreements are still pending, at least one study has begun enrolling patients under a clinical institution IRB approval.

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***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 just signed a 3-year extension of 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 ovarian cancer diagnostic 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. The PAD intended use study, titled "A validated biomarker panel to identify peripheral artery disease," and published in the December 2012 edition of *Vascular Medicine*, was authored by Dr. William Hiatt, Novartis Foundation endowed professor for cardiovascular research at the University of Colorado School of Medicine, Division of Cardiology. The article reported the results of a multi-center, prospective clinical study of 1,025 subjects, consecutively enrolled from the PAD at-risk population of those aged 70 or older, and diabetics and smokers 50 or older. Several different multi-marker algorithms were evaluated in at-risk patients with or without PAD, and compared to conventional cardiovascular risk assessment by the Framingham Risk Score (FRS). The best model demonstrated a c-statistic of 0.73 and more important, identified 17 of 20 (85%) of patients with PAD who were missed by the FRS high-risk cutoff. Similar results were seen in asymptomatic PAD subjects, where the algorithm correctly classified 84% (48/57). In a statement, the study's co-author Dr. Cooke commented, "Since one in every 20 Americans over the age of 50 has PAD, this study suggests the possibility for a simple and practical way to screen at-risk patients. By detecting undiagnosed or asymptomatic PAD, primary care physicians can intervene earlier and improve the health and prognosis for their patients. We are truly excited at the confirmation our biomarker research achieved in this large group of at-risk subjects, and look forward to advancing our program."

Our PAD achievements, intellectual property and publications will support future discussions with potential development/ commercial partners and help to define the appropriate validation pathway, which may be as an FDA-approved or cleared test, or as a Laboratory Developed Test validated under the auspices of a CLIA-regulated clinical laboratory. Our path forward is to evaluate partnering options for the PAD program with third parties who have substantial presence in the cardiovascular market, as well as the funding and development capabilities to take this important blood test to market.

Our research and development expenses were \$2,216,000 and \$5,387,000 for the years ended December 31, 2012 and 2011, respectively. The decrease from the prior year was due primarily to a decrease in clinical trial costs for the ongoing development of our ovarian cancer franchise and our PAD program as our PAD intended use study was completed in 2011. The clinical trial cost decrease was net of ongoing expenses for our OVA1 FDA post-marketing study that commenced during 2012.

**Commercial Operations**

We have a commercial infrastructure, including sales and marketing and reimbursement expertise. Our sales representatives work with 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.

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At the end of 2012, approximately 16,460 OVA1 tests had been performed in the calendar year, an increase of 8% over 2011. Additionally, we estimate 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 2012, over 5,300 doctors had ordered the test, an increase of 43% over 2011.

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.

In 2013, our Territory Development Managers will also be targeting key hospital accounts that are interested in providing OVA1 results to their OB/GYN and GYN/ONC physicians. These hospitals must have the required instrumentation as required in our product requirements insert to be eligible to perform the OVA1 risk algorithm.

There are still obstacles to overcome and significant milestones to attain to insure 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 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.

### **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. In 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, 2013, twenty-seven independent BlueCross BlueShield plans, representing more than 46.8 million lives, provide coverage for OVA1. In total, including Medicare and other private payers, approximately 93.3 million patients have access and coverage for OVA1. The Company and Quest Diagnostics continue to pursue 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, which became effective January 1, 2013. The new CPT code is a positive step forward in advancing the commercialization of OVA1, as we believe it 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 payer 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 at the time of its 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 implemented. Now, after establishing OVA1 in the market, creating demand, demonstrating the utility of the test, obtaining coverage and reimbursement, we filed for a CPT code specific for OVA1 in 2011, which was effective beginning January 1, 2013. Achieving the unique Category I CPT code # 81503 was a critical step our commercialization process.

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The test is priced in 2013 by the Centers for Medicare and Medicaid Services (CMS) using their gap-fill process. CMS uses this process when no comparable test exists. Medicare currently reimburses OVA1 at \$516 per test and our test list price is \$650.

### Claims Process

In the early launch of a product, 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.

### Payer Coverage

We continue to focus on going efforts toward obtaining national coverage decisions. However, these decisions 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 customer's 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 combines two tumor markers and menopausal status into a numerical score using a publicly available algorithm. This test has the same intended use and precautions as OVA1. The Risk of Ovarian



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Malignancy Algorithm is currently marketed as having utility limited to epithelial ovarian cancers, which accounts for 80% of ovarian malignancies. The two tests have not been compared in a side by side cohort evaluation to date, so no direct performance comparisons can be made.

### **Intellectual Property Protection**

Our intellectual property includes a portfolio of owned, co-owned or licensed patents and patent applications. As of December 31, 2012, our clinical diagnostics patent portfolio included 24 issued United States patents, 14 pending United States patent applications, and numerous pending patent applications and issued patents outside the United States. These patents and patent applications fall into 32 patent families and are directed to several areas of technology important to our business, including ovarian cancer, breast cancer, PAD, Alzheimer's and other clinical diagnostic technologies. 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.

For intellectual property derived from Surface-Enhanced Laser Desorption/Ionization ( SELDI ) technology, 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.

The patent portfolio enumerated above also includes intellectual property which was acquired, together with other clinical diagnostics assets from Correlogic, Inc.

On May 8, 2012 the United States Patent and Trademark Office ( USPTO ) granted patent number 8,173,433, titled 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 June 26, 2012, the USPTO granted patent number 8,206,934, titled Methods for diagnosing ovarian cancer. This patent further expands the list of biomarkers Vermillion has employed in the diagnosis or status determination of ovarian cancer. In this patent, the granted claims cover the use of Protein C Inhibitor (PCI) in ovarian cancer tests using blood and several other sample types.

On July 17, 2012, the USPTO granted patent number 8,221,984, titled Biomarkers for ovarian cancer. The patent makes claims in the uses of a urinary Small MBL-associated protein C-terminal fragment (sMAP) in the diagnosis of ovarian cancer, ovarian cancer monitoring, and patient management.

On July 24, 2012, the USPTO granted patent number 8,227,201, titled Beta2-microglobulin and C reactive protein (CRP) as biomarkers for peripheral artery disease. The patent contains claims to the use of beta2-microglobulin (B2M) and CRP to diagnose PAD in patients with risk factors of symptoms of cardiovascular disease, as well as a software classification algorithm, test reports or computer displays, and managing the treatment of such a patient. 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.

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 2013 and \$100,000 for 2014. Collaboration costs under the JHU collaboration were \$251,000 and \$235,000 for the years ended December 31, 2012 and 2011,

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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 \$57,500. 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.

### **Manufacturing**

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

### **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



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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 our PAD test and our next generation ovarian cancer test. 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.

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

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the FDA, which prohibits the marketing of medical devices for unapproved uses. Additionally, the FDA requires us to perform certain post-marketing studies ( Post-market Surveillance ) to verify or validate the clinical performance of FDA-cleared tests, as is permitted by their statutory authority.

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 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, 2012, we had 20 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](http://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](http://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](http://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

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**ITEM 1A. RISK FACTORS**

*You should carefully consider the following risk factors and uncertainties together with all of the other information contained in this 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.*

**Risks Related to Our Business**

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

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

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

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

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

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

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

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

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

In order to continue our operations through 2013 and beyond, we will need to raise additional capital. Our independent registered public accounting firm's report on our financial statements for the year ended December 31, 2012 includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern, given our recurring net losses and negative cash flows from operations. We may seek to raise additional capital through the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. The availability of financing opportunities will depend, in part, on market conditions, and the outlook for our business. Any future issuance of equity securities or securities convertible into equity could result in substantial dilution to our stockholders, and the securities issued in such a financing may have rights, preferences or privileges senior to those of our common stock. 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

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be required to relinquish rights to certain technologies or products that we might otherwise seek to retain. If adequate and acceptable financing is not available to us at the time that we seek to raise additional capital, our ability to execute our business plan successfully may be negatively impacted.

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

Our success depends on our ability to continue to develop and commercialize diagnostic products. There is considerable risk in developing diagnostic products based on our biomarker discovery efforts, as candidate biomarkers may fail to validate results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. For example, markers being evaluated for 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 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.

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

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

our success in establishing new clinical practices or changing previous ones, such that utilization of the tests fail to meet established standards of care, medical guidelines and the like;

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

the scope and extent of the agreement by Medicare and third-party payers to provide full or partial reimbursement coverage for our products, which will affect patients' willingness to pay for our products and will likely heavily influence physicians' decisions to recommend or use our products.

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

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

Our principal competition currently comes from the many clinical options available to medical personnel involved in clinical decision making. For example, rather than ordering an OVA1 for a woman with an adnexal mass, obstetricians, gynecologists, and gynecologic oncologists may choose a different clinical option or none at all. If we are not able to convince clinicians that OVA1 provides significant improvement over current clinical practices, our ability to commercialize OVA1 would be adversely affected. Additionally, Fujirebio Diagnostics, Inc. announced in September 2011 that they have received clearance from the FDA to commercialize its Risk of Malignancy Algorithm ( ROMA ) test. The ROMA test may be in direct competition with OVA1 and our



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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.

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,

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

The commercialization of our OVA1 test depends on the supply of five different immunoassay kits from third-party manufacturers. Failure by any of these manufacturers to produce kits that pass Vermillion s quality control measures might lead to back-order and/or loss of revenue due to missed sales and customer dissatisfaction. In addition, if the design or labeling of any kit were to change, continued OVA1 supply could be threatened since new validation and submission to the FDA for 510(k) clearance could be required as a condition of sale. Discontinuation of any of these kits would require identification, validation and 510(k) submission on a revised OVA1 design. While Vermillion has experienced no such issues to date, there can be no assurances that this will not occur in the future.

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

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

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

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



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

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

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

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

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

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

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

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

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

*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.

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

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

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

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

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

*If we fail to maintain proper and effective internal controls, 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.

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

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

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

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

### **Risks Related to Owning our Stock**

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

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

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

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;

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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.

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

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

In order to maintain the listing on the Nasdaq Capital Market, we must satisfy minimum financial and other requirements, including requirements that we maintain a minimum stockholders' equity of \$2.5 million and a minimum bid price of \$1 per share. If we fail to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and adversely affect our ability to obtain financing for the continuation of our operations. This delisting could also impair the value of our investors' investment.

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

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us, even if doing so might be deemed beneficial by our stockholders. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company.

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

## Edgar Filing: VERMILLION, INC. - Form 10-K

Certain of our stockholders may, from time to time, attempt to aggressively involve themselves in the governance and strategic direction of our Company above and apart from normal interactions between stockholders and management. Such activism, and any related negative publicity, could result in substantial costs that negatively impact our stock price and increase its volatility. In addition, such activism could cause a diversion of the attention of our management and Board of Directors and create perceived uncertainties with existing and potential strategic partners impacting our ability to consummate potential transactions,

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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.

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

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

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

As of December 31, 2012, we had 15,200,079 shares of our common stock outstanding and 22,471 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes 1,092,374 shares of our common stock that were subject to outstanding options. In addition, as of December 31, 2012, warrants to purchase 63,000 shares of our common stock were outstanding at an exercise price of \$2.78 per share.

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

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

We have a limited number of shares available under the 2010 Stock Incentive Plan (the "2010 Plan"). We are seeking stockholder approval of an increase in the number of shares available for issuance under the 2010 Plan, but there can be no assurances that such increase will be approved. We have historically used stock options as a significant component of our employee compensation program in order to align employees' interests with the interests of our stockholders, encourage employee retention, and provide competitive compensation packages. We currently have an interim chief executive officer and are in the process of searching for a permanent chief executive officer. If we are unable to increase the number of shares available under the 2010 Plan, our ability to offer attractive equity incentive awards in the future may be limited or nonexistent and may make it more difficult for us to attract, retain and motivate key personnel, including a permanent chief executive officer.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**Table of Contents****ITEM 2. PROPERTIES**

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

<b>Location</b>	<b>Approximate Square Feet</b>	<b>Primary Functions</b>	<b>Lease Expiration Date</b>
Austin, Texas	4,218 sq. ft.	Research and development, clinical and regulatory, marketing, sales and administrative offices	2014

**ITEM 3. LEGAL PROCEEDINGS*****Robert Goggin and György Bessenyei Litigation***

On May 25, 2012, György B. Bessenyei and Robert S. Goggin, III, both stockholders of Vermillion, filed a verified complaint in the Delaware Court of Chancery (the Court) against Vermillion, each current member of our Board of Directors, and Gail S. Page. On June 1, 2012, Mr. Bessenyei and Mr. Goggin filed an amended verified complaint that was substantially similar to the verified complaint. The amended verified complaint contains the following causes of action: breach of fiduciary duty under two standards, declaratory relief, preliminary injunctive relief, and permanent injunctive relief. The allegations in the amended verified complaint challenge the recent adoption by the Board of Directors of an amendment to our bylaws eliminating the board seat formerly held by Ms. Page. As previously disclosed by Vermillion, on May 15, 2012, Ms. Page was terminated without cause as Vermillion's President and Chief Executive Officer (CEO), and, upon her termination, Ms. Page resigned her seat on the Board of Directors. For a variety of reasons, including an effort to streamline Vermillion's organization and extend its cash runway, the Board of Directors amended our bylaws to eliminate the vacant board seat, thereby reducing the size of the Board of Directors from seven to six members. This effort to streamline Vermillion's organization had begun in January 2012, when the Board of Directors amended the bylaws to eliminate an additional (eighth) seat on the Board of Directors. Mr. Bessenyei and Mr. Goggin claim that the Board of Directors' decision to eliminate the seat on May 15, 2012 was a breach of its fiduciary duties, alleging that the Board of Directors actions were intended to prevent Mr. Bessenyei's and Mr. Goggin's nominees from both being able to be elected to the Board of Directors, and to entrench the Board of Directors' current members. Among other things, Mr. Bessenyei and Mr. Goggin sought to have the Court declare null and void the May 15, 2012 amendment to the bylaws, and award to Mr. Bessenyei and Mr. Goggin the costs and fees incurred by them in the action.

The parties negotiated a scheduling order, which was approved on June 6, 2012, setting trial in this expedited action to start on July 31, 2012. On June 13, 2012, Vermillion and the other defendants filed an answer. The parties then engaged in extensive discovery, including document production, service of interrogatory responses, and the taking of depositions. On July 26, 2012, Vermillion and the other defendants filed a motion to dismiss the case arguing that plaintiffs and their counsel improperly notarized documents verifying the complaint, amended complaint and discovery responses. On November 16, 2012, the Court dismissed the lawsuit with prejudice. The plaintiffs filed a notice of appeal of that dismissal order on December 10, 2012, and filed their opening appellate brief on February 1, 2013. On February 12, 2013, the Delaware Supreme Court denied Vermillion and the other defendants' motion to summarily affirm. Vermillion and the other defendants are in the process of preparing an appellate answering brief which will be filed by March 4, 2013. No hearing date on the appeal has been set by the Delaware Supreme Court.

***György Bessenyei Annual Shareholder Meeting Litigation***

On January 9, 2013, György B. Bessenyei, a stockholder of Vermillion, filed a verified complaint in the Delaware Court of Chancery (the Court) against Vermillion, and each current member of our Board of Directors. The complaint contains a cause of action for violation of Section 211 of the General Corporation Law

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of Delaware. The allegations in the complaint relate to the 2012 annual shareholder meeting which had not yet been held due to a scheduling order entered in the Goggin and Bessenyei litigation discussed above. The complaint seeks to have the Court compel Vermillion to hold its annual shareholder meeting and to award to Mr. Bessenyei the costs and fees incurred by him in the action. On January 16, 2013, the parties held a scheduling conference with the Court. On January 18, 2013, Vermillion filed its preliminary proxy setting the annual meeting date for March 21, 2013. Thereafter, both parties submitted competing proposed orders related to the upcoming annual shareholder meeting. The Court has not yet signed either order.

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 are deemed 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.



**Table of Contents****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 January 24, 2013, there were 68 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 February 20, 2013 was \$1.38.

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

	2012		2011	
	High	Low	High	Low
First Quarter	\$ 3.02	\$ 1.19	\$ 9.25	\$ 3.75
Second Quarter	2.79	1.62	7.60	3.33
Third Quarter	2.36	1.56	4.36	2.14
Fourth Quarter	1.88	1.13	2.89	0.97

**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.

**Unregistered Sales of Equity Securities**

None.

**Equity Compensation Plan Information**

We currently maintain two equity-based compensation plans that were approved by our stockholders. The plans are the Amended and Restated 2000 Stock Plan (the 2000 Plan), 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, 2012, options to purchase 336,656 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, 2012, options to purchase 755,718 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, 2012, were as follows:

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Shares Reflected in First Column)</b>
Equity compensation plans approved by security holders	1,092,374 <sup>(1)</sup>	\$ 4.17 <sup>(2)</sup>	22,471 <sup>(3)</sup>
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>1,092,374</b>		<b>22,471</b>

- (1) Includes outstanding stock options for 336,656 shares of our common stock under the 2000 Plan and 755,718 shares of our common stock under the 2010 Plan.
- (2) Includes the weighted average stock price for outstanding stock options of \$7.22 under the 2000 Plan and \$2.82 for the 2010 Plan.
- (3) Includes 22,471 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.

**Table of Contents****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 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.

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 95.7% (154/161) of the malignant ovarian tumors overall, and to rule out malignancy with a negative predictive value (NPV) of 94.6% (123/130). 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.

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

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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 37,840 OVA1s have been performed from the launch on March 9, 2010 through December 31, 2012.

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 completed an intended-use study to develop and validate a multi-marker algorithm for the assessment of individuals at risk for peripheral arterial disease in 2011. This algorithm will be specifically directed at a primary care population in which the peripheral arterial disease blood test is expected to be used. We plan to seek a Development/Commercial Partner for this product opportunity who will work with us to complete the product development, complete the required FDA studies for approval, and eventually commercialize this product opportunity on a global basis. 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 February 9, 2012, we entered into a Settlement Agreement and Release (the Settlement Agreement) with Oppenheimer & Co., Inc. (Oppenheimer) related to losses on our short and long-term investments in previous years. Under the terms of the Settlement Agreement, we received a total settlement of \$1,000,000; \$535,000 was paid in March 2012 and \$465,000 was paid in August 2012. We received approximately \$710,000 of the total settlement, 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, which became effective January 1, 2013.

On March 28, 2012, we announced the receipt of a notice of allowance from the USPTO for a patent, Methods for Diagnosing Ovarian Cancer. This patent further expands the list of biomarkers we have employed in the diagnosis or status determination of ovarian cancer. In this case, the granted claims cover the use of Protein C Inhibitor (PCI) in ovarian cancer tests using blood and several other sample types.

On April 16, 2012, we announced the receipt of a notice of allowance from the USPTO for a patent, Biomarkers for Ovarian Cancer. The patent makes claims in the uses of a urinary Small MBL-associated protein C-terminal fragment (sMAP) in the diagnosis of ovarian cancer, ovarian cancer monitoring, and patient management.

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On April 30, 2012, we announced the resolution of four non-contingent contract claims made by Bio-Rad arising from the Instrument Business Sale. In exchange for a final settlement of the non-contingent claims, Bio-Rad received \$700,000 from an escrow account established by the Company for the sale transaction and the Company received approximately \$1,080,000 from the escrow account.

On May 15, 2012, we announced our CEO succession plan beginning the process of identifying a successor to Gail S. Page, president and CEO. Our Board of Directors formed a search committee as part of the leadership succession plan and Ms. Page resigned from the Board of Directors.

On June 15, 2012, we announced that results of the recent PAD multi-marker intended use study were presented at the Society for Vascular Medicine's 23rd Annual Scientific Sessions, in Minneapolis, Minnesota. This meeting hosted the nation's leading vascular medicine specialists, and included sessions on PAD guidelines, policy trends, and advances in the diagnosis and treatment of vascular diseases.

The poster presented to the meeting was authored by Professor of Medicine and Associate Director of Stanford Cardiovascular Institute Dr. John Cooke, together with colleagues at the University of Colorado and is entitled "Results of a Biomarker Screen to Identify Peripheral Artery Disease." It reported the results of a multi-center clinical study involving 1,025 subjects, prospectively enrolled from the PAD at-risk population of subjects aged 70 or older, and diabetics and smokers 50 or older.

Different multi-marker algorithms were evaluated in patients with or without PAD, in comparison with the Framingham Risk Score (FRS). The multi-marker models were also assessed for their ability to identify PAD in patients below the high-risk FRS cutoff. The best model demonstrated a c-statistic of 0.73 and more importantly, identified 17 of 20 (85%) of patients missed by the FRS high-risk cutoff.

On July 30, 2012, we announced positive results from a new prospective, multi-center clinical study of our ovarian cancer diagnostic OVA1<sup>®</sup>. The study, referred to as OVA500, was led by Dr. Robert E. Bristow, director of Gynecologic Oncology Services at University of California Irvine Healthcare in Orange, California, and deputy editor of the journal Gynecologic Oncology.

The OVA500 study confirms and extends the pioneering work of Dr. Fred Ueland published last year. It was a prospective, multi-institutional, blinded study with a new cohort of 494 patients representing the intended use population for OVA1: female patients who were scheduled to undergo surgery for an adnexal mass, enrolled from non-gynecologic oncology practices via 27 study coordination centers.

All adnexal tumor types were included in the statistical analysis of test performance. The primary objective was to assess the performance of OVA1 in the intended use population with a focus on two particularly challenging subgroups: women with early-stage ovarian cancer, where approximately half of patients have a normal CA125 level, and pre-menopausal women, where the incidence of ovarian cancer is low and incidence of benign cysts is high.

Top-line data from the study are as follows:

**Overall Performance of OVA1**

Negative predictive value was reported at 98%

Sensitivity was reported at 96%

Specificity was reported at 51%

**Performance in the Pre-menopausal Population**

Sensitivity was reported at 94%

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**Performance for Early-Stage Ovarian Cancer (I and II)**

Sensitivity was reported at 91%

**OVA1 as a Risk Stratification Test (OVA1 score versus cutoff, independent of physician assessment)**

Sensitivity was reported at 92% overall:

91% for early-stage disease

94% for pre-menopausal patients

91% for stage I and II in pre-menopausal women with a specificity of 61%

The OVA500 results were subsequently published online by *Gynecologic Oncology* on November 22, 2012 in the article, Ovarian Malignancy Risk Stratification of the Adnexal Mass Using a Multivariate Index Assay.

On October 12, 2012, we announced the payment to Quest Diagnostics of approximately \$5,901,000, which we believe represents payment in full of all outstanding principal and interest under the Secured Line of Credit Agreement dated as of July 22, 2005 between the Company and Quest Diagnostics. The payoff incorporated \$1,000,000 in additional principal forgiveness under the terms of the Strategic Alliance and \$106,000 in previous principal curtailment payments. However, Quest Diagnostics has disputed that such milestone forgiveness was achieved or principal curtailment was made. This disputed amount of \$1,106,000 is reported as short-term debt on our consolidated balance sheet at December 31, 2012.

On November 16, 2012, we announced that the Delaware Court of Chancery dismissed with prejudice a lawsuit brought against Vermillion, Inc. and its board of directors by dissident stockholders, Gyorgy B. Bessenyei and Robert S. Goggin, III.

Following the decision, a proxy filed with the Securities Exchange Commission (SEC) by an alleged stockholder group led by Bessenyei and Goggin describes Goggin as honest and trustworthy. However, the Delaware Court of Chancery court issued findings to the contrary. The court ruled that Goggin and Bessenyei had illegally falsified documents by improperly notarizing court filings in connection with the lawsuit and, moreover, that the conduct of Goggin appeared to be a violation of the Pennsylvania rules of professional conduct applicable to Pennsylvania lawyers.

With the suit now dismissed with prejudice, which disallows its re-filing, we were able to move forward with our annual meeting. The meeting had been delayed due to the Bessenyei and Goggin lawsuit, which prohibited the company from holding a meeting until the matter was resolved.

On November 27, 2012, we announced the appointment of director Bruce A. Huebner as Interim Chief Executive Officer. He succeeded Gail S. Page, who had assisted in the transition and served as a strategic advisor to the company as requested by its board of directors. Mr. Huebner continues to serve on our board of directors.

On January 3, 2013, the Company received a letter (the Delisting Notice) from the NASDAQ Stock Market LLC (NASDAQ) notifying the Company that it is not in compliance with NASDAQ's Listing Rule 5620(a), which requires the Company to hold an annual meeting of shareholders no later than one year after the end of the Company's fiscal year-end, and Listing Rule 5620(b), which requires the Company to solicit proxies and provide proxy statements for such meeting and to provide copies of such proxy solicitation to NASDAQ. The Delisting Notice stated that unless the Company requested an appeal of this determination, trading of the Company's common stock would be suspended on January 14, 2013, and a Form 25-NSE would be filed with the SEC, which would remove the Company's securities from listing and registration on NASDAQ. The Company filed an appeal which stayed the delisting action while the appeal is pending.



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The annual meeting was delayed due to a lawsuit brought against the Company and its board of directors by dissident stockholders, Gyorgy B. Bessenyei and Robert S. Goggin, III, which prohibited the Company from

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holding a meeting until the matter was resolved. As previously announced by the Company, the case was dismissed with prejudice on November 16, 2012. The Company has scheduled the 2012 Annual Meeting for March 21, 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 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.

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 sufficient 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.

#### *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.

#### *Patent Costs*

Costs incurred in filing, prosecuting and maintaining patents (principally legal fees) are expensed as incurred and recorded within selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss. Such costs aggregated approximately \$312,000 and \$363,000 for the years ended December 31, 2012 and 2011, respectively.

#### *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

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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.

### *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 adopted this pronouncement in the first quarter of 2012, and it had no effect on our financial position, results of operations or cash flows but did impact the way we present comprehensive income.

**Table of Contents****Results of Operations Year Ended December 31, 2012 as compared to Year Ended December 31, 2011**

The selected summary financial and operating data of Vermillion for the years ended December 31, 2012 and 2011 were as follows:

(dollars in thousands)	Year Ended December 31,		Increase (Decrease)	
	2012	2011	Amount	%
<b>Revenue:</b>				
Product	\$ 1,640	\$ 1,469	\$ 171	12
License	454	454		
<b>Total revenue</b>	<b>2,094</b>	<b>1,923</b>	<b>171</b>	<b>9</b>
<b>Cost of revenue:</b>				
Product	131	129	2	2
<b>Total cost of revenue</b>	<b>131</b>	<b>129</b>	<b>2</b>	<b>2</b>
<b>Gross profit</b>	<b>1,963</b>	<b>1,794</b>	<b>169</b>	<b>9</b>
<b>Operating expenses:</b>				
Research and development	2,216	5,387	(3,171)	(59)
Sales and marketing	4,653	5,539	(886)	(16)
General and administrative	4,508	8,509	(4,001)	(47)
<b>Total operating expenses</b>	<b>11,377</b>	<b>19,435</b>	<b>(8,058)</b>	<b>(41)</b>
<b>Loss from operations</b>	<b>(9,414)</b>	<b>(17,641)</b>	<b>8,227</b>	<b>(47)</b>
Interest income	28	64	(36)	(56)
Interest expense	(206)	(396)	190	(48)
Gain on sale of instrument business	1,830		1,830	
Gain on litigation settlement, net	710		710	
Change in fair value of warrants		378	(378)	
Reorganization items	88	(96)	184	(192)
Other expense, net	(182)	(99)	(83)	84
<b>Loss before income taxes</b>	<b>(7,146)</b>	<b>(17,790)</b>	<b>10,644</b>	<b>(60)</b>
<b>Income tax benefit (expense)</b>				
<b>Net loss</b>	<b>\$ (7,146)</b>	<b>\$ (17,790)</b>	<b>\$ 10,644</b>	<b>(60)</b>

**Product Revenue.** Product revenue was \$1,640,000 for the year ended December 31, 2012 compared to \$1,469,000 for the same period in 2011. We recognized product revenue for the year ended December 31, 2012 for the sale of OVA1 through Quest Diagnostics. Quest Diagnostics performed approximately 16,460 OVA1 tests during the year ended December 31, 2012 compared to approximately 15,225 tests for the same period in 2011. Product revenue increased \$171,000 for the year ended December 31, 2012 compared to the same period in 2011 due to the increased volume of tests as well as the recognition of deferred revenue upon meeting the criteria for revenue recognition. We recognized \$816,000 of deferred revenue in 2012 upon receipt of an annual royalty report from Quest Diagnostics. During 2011, we recognized \$549,000 of deferred revenue related to 2011 in addition to \$160,000 of deferred revenue related to 2010 upon receipt of two annual royalty reports from Quest Diagnostics.

The 2012 annual royalty report of \$816,000 was based upon 13,709 OVA1 tests reported by Quest Diagnostics as resolved in 2012, or an average of \$60 per test resolved. The resolved volume includes both reimbursed and unreimbursed tests for which the payment status was considered final by Quest Diagnostics as of December 31, 2012. Tests that do not yet have a final resolution for 2012 will be included in a future annual royalty report. By comparison, the 2011 annual royalty report of \$549,000 was based upon 11,708 OVA1 tests reported by Quest Diagnostics as resolved in 2011, or an average of \$47 per test resolved. The royalty report revenue is incremental to the fixed \$50 per test recognized for each OVA1 performed during the year.



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**Research and Development Expenses.** Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with our collaborators and strategic partners. Research and development expenses decreased by \$3,171,000, or 59%, for the year ended December 31, 2012 compared to the same period in 2011. This decrease was due primarily to a \$2,457,000 decrease in clinical trial costs for the ongoing development of our ovarian cancer franchise and our PAD program as our PAD intended use study was completed in 2011. The clinical trial cost decrease was net of ongoing expenses for our OVA1 FDA post-marketing study that commenced during 2012. In addition, stock compensation costs decreased \$554,000 compared to the same period in 2011. We anticipate that research and development expenses will increase in future periods due to costs of the FDA post-marketing study.

**Sales and Marketing Expenses.** Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and health economic publications. Our personnel-related expenses include the cost of our Territory Development Managers, the subject matter experts responsible for market development and the coordination of interactions with the Quest Diagnostic's sales team. Sales and marketing expenses decreased by \$886,000, or 16%, for the year ended December 31, 2012 compared to the same period in 2011. The decrease was due primarily to a \$538,000 reduction in personnel and personnel-related expenses related to lower headcount in 2012 compared to 2011. In addition, advertising, medical education and trade show expenses decreased \$545,000 compared to the same period in 2011 due to decreased print advertising compared to 2011 and fewer events being sponsored in 2012.

**General and Administrative Expenses.** General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses, and other infrastructure expenses. General and administrative expenses decreased by \$4,001,000, or 47%, for the year ended December 31, 2012 compared to the same period in 2011. The decrease was due to \$1,486,000 in lower stock compensation expenses as there were no bankruptcy-related stock compensation costs in 2012 (the Debtor's Incentive Plan was fully amortized at June 30, 2011). Personnel and personnel-related expenses also decreased \$749,000 due to the departure of both our Chief Financial Officer and Vice President of Corporate Strategy. In addition, 2012 included a one-time reversal of \$375,000 of amounts previously accrued for the Bio-Rad claims and audit and legal fees decreased \$1,593,000 compared to calendar 2011 due to a decrease in overall activity and as 2012 legal expenses were recorded net of expenses incurred which have been or are anticipated to be covered and paid directly by our insurance carrier. These decreases were partially offset by a one-time charge for CEO severance of approximately \$400,000 in the year ended December 31, 2012.

**Interest Expense.** Interest expense decreased by \$190,000, or 48%, for the year ended December 31, 2012 compared to the same period in 2011 as we paid off \$5,000,000 of our 7.00% Senior Convertible Notes upon maturity in September 2011 and \$5,894,000 of short-term debt to Quest upon maturity in October 2012.

**Gain on sale of instrument business.** Gain on sale of instrument business was \$1,830,000 for the year ended December 31, 2012. This gain was derived from the return in 2012 of funds held in escrow from our 2006 sale of the instrument business to Bio-Rad.

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

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**Change in fair value of warrants.** There was no change in fair value of warrants for the year ended December 31, 2012 compared to \$378,000 for the same period in 2011. This decrease of \$378,000 was due primarily to the relative decrease in the Company's stock price during 2011.

**Reorganization items.** Reorganization items were income of \$88,000 for the year ended December 31, 2012 compared to expense of \$96,000 for the same period in 2011. The increase was due to the one-time recognition of \$103,000 in claims adjustments upon the formal closure of our voluntary petition for relief (our Bankruptcy Filing) under Chapter 11 of the United States Bankruptcy Code (Chapter 11) in the United States Bankruptcy Court for the District of Delaware (the Bankruptcy Court) in January 2012 as well as minimal ongoing reorganization costs in 2012.

**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,		Increase (Decrease)	
	2011	2010	Amount	%
<b>Revenue:</b>				
Product	\$ 1,469	\$ 308	\$ 1,161	377
License	454	867	(413)	(48)
<b>Total revenue</b>	<b>1,923</b>	<b>1,175</b>	<b>748</b>	<b>64</b>
<b>Cost of revenue:</b>				
Product	129	88	41	47
<b>Total cost of revenue</b>	<b>129</b>	<b>88</b>	<b>41</b>	<b>47</b>
<b>Gross profit</b>	<b>1,794</b>	<b>1,087</b>	<b>707</b>	<b>65</b>
<b>Operating expenses:</b>				
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)
<b>Total operating expenses</b>	<b>19,435</b>	<b>15,689</b>	<b>3,746</b>	<b>24</b>
<b>Loss from operations</b>	<b>(17,641)</b>	<b>(14,602)</b>	<b>(3,039)</b>	<b>21</b>
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)
<b>Loss before income taxes</b>	<b>(17,790)</b>	<b>(19,034)</b>	<b>1,244</b>	<b>(7)</b>
Income tax benefit (expense)				
<b>Net loss</b>	<b>\$ (17,790)</b>	<b>\$ (19,034)</b>	<b>\$ 1,244</b>	<b>(7)</b>

**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





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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 of 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 of 2,814 tests. Tests which do not yet have final resolution will be included in a future 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 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 as well as \$435,000 for the Correlologic 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.

**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.

**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

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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 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 Correlologic 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.

**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.

**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.

## **Liquidity and Capital Resources**

On March 9, 2010, we launched OVA1 commercially. 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. We paid \$5,000,000 in September 2011 to repay the outstanding 7.00% Notes. We paid \$5,894,000 in October 2012 to repay the Secured Line of Credit with Quest Diagnostics. As of December 31, 2012, we have \$1,106,000 reported as short-term debt on our consolidated balance sheet that is in dispute with Quest Diagnostics.

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We have incurred significant net losses and negative cash flows from operations since inception. At December 31, 2012, we had an accumulated deficit of \$323,445,000 and stockholders' equity of \$4,667,000. On December 31, 2012, we had \$8,007,000 of cash and cash equivalents and \$3,197,000 of current liabilities.

We expect cash for OVA1 from Quest Diagnostics to be our only material, recurring source of cash in 2013. 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 may seek to raise capital through a variety of sources, including the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and/or public or private debt.

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

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

resources devoted to establish sales, marketing and distribution capabilities;

the rate of product adoption by physicians and patients;

our determination to acquire or invest in other products, technologies and businesses;

the market price of our common stock as it affects the exercise of stock options; and

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

Cash and cash equivalents as of December 31, 2012 and December 31, 2011 were \$8,007,000 and \$22,477,000, respectively. At December 31, 2012 and 2011, working capital was \$5,295,000 and \$11,417,000, respectively.

Net cash used in operating activities was \$10,398,000 for the year ended December 31, 2012, resulting primarily from \$7,146,000 net loss incurred as adjusted for completion of the 2006 gain on sale of instrument business to Bio-Rad of \$1,830,000 and non-cash license revenues of \$454,000, partially offset by \$1,295,000 of stock-based compensation expense. Net cash used in operating activities also included \$2,472,000 of cash used from changes in operating assets and liabilities mainly driven by the \$2,292,000 decrease of accounts payable and accrued liabilities.

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 provided by investing activities for the year ended December 31, 2012 was \$1,816,000 due primarily to the receipt of escrow funds upon completion of the 2006 sale of instrument business to Bio-Rad. Net cash used in investing activities was \$99,000 for the year ended December 31, 2011, due to the purchase of property and equipment.

Net cash used in financing activities was \$5,888,000 for the year ended December 31, 2012, which resulted primarily from our \$5,894,000 repayment of short-term debt with Quest Diagnostics in October 2012.



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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.

**Off-Balance Sheet Arrangements**

As of December 31, 2012, 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, 2012 and 2011, consolidated statements of operations and comprehensive loss for the years ended December 31, 2012 and 2011, consolidated statements of changes in stockholders' equity for the years ended December 31, 2012 and 2011, consolidated statements of cash flows for the years ended December 31, 2012 and 2011 and notes to our consolidated financial statements, together with reports thereon of our independent registered public accounting firms, dated March 1, 2013 and March 26, 2012, are attached hereto as pages F-1 through F-27.

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

On April 4, 2012, we dismissed PricewaterhouseCoopers LLP ( PwC ) as our independent registered public accounting firm, upon approval of the Audit Committee of the Board of Directors.

The audit reports issued by PwC for the years ended December 31, 2010 and December 31, 2011 did not contain any adverse opinion or disclaimer of opinion, nor were the reports qualified or modified as to uncertainty, audit scope or accounting principles, except that the audit reports on the Company's financial statements for the years ended December 31, 2010 and December 31, 2011 included an explanatory paragraph noting that the Company voluntarily filed for Chapter 11 bankruptcy protection on March 30, 2009 and subsequently emerged from bankruptcy on January 22, 2010, and the audit report on the Company's financial statements for the year ended December 31, 2011 also included an explanatory paragraph noting that there was substantial doubt about the Company's ability to continue as a going concern.

During the years ended December 31, 2010 and December 31, 2011 and through April 4, 2012, the Company did not have any disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) with PwC on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of PwC, would have caused PwC to make reference thereto in its report on the Company's financial statements for such years. Also, during the years ended December 31, 2010 and December 31, 2011 and through April 4, 2012, there have been no reportable events as that term is defined in Item 304(a)(1)(v) of Regulation S-K, except that, as disclosed in Item 4 of the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010, June 30, 2010 and September 30, 2010, management of the Company concluded that because the Company filed for Chapter 11 bankruptcy protection on March 30, 2009, the Company did not maintain sufficient staff with the necessary experience in U.S. generally accepted accounting principles to timely perform its controls procedures relating to the accounting and reporting processes. Specifically, the Company did not have sufficient accounting and reporting expertise necessary to make estimates requiring significant judgment or

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to record complex transactions in a manner necessary to facilitate the timely filing of all Forms required by the Exchange Act of 1934, as amended, and as a result, the Company was not able to timely file all Forms required by the Exchange Act. Therefore, management concluded that this control deficiency constituted a material weakness as of March 31, 2010, June 30, 2010 and September 30, 2010.

On April 4, 2012, the Audit Committee approved the engagement of BDO USA, LLP ( BDO ) as the Company's new independent registered public accounting firm to audit the Company's financial statements as of and for the year ending December 31, 2012. The Company will ask stockholders at the 2012 annual meeting of stockholders to ratify the appointment of BDO as the Company's independent registered public accounting firm for the year ended December 31, 2012.

During the years ended December 31, 2010 and December 31, 2011, and through April 4, 2012, the Company did not consult BDO with respect to either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the Company's financial statements, and no written report or oral advice was provided to the Company by BDO that was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(2)(ii) of Regulation S-K.

**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.

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, 2012.

Based on that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of December 31, 2012 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, 2012. 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;

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- (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, 2012 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, 2012, 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, 2012 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**  
**Information Regarding Directors**

Our Board of Directors currently consists of six directors, following the reduction in size authorized by the Board of Directors to eliminate the vacancy due to the resignation of Ms. Page. The directors are divided into three classes having staggered three-year terms, so that the term of one class expires at each annual meeting of stockholders. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of an equal number of directors. The classes are currently comprised as follows:

*Class I directors.* Bruce A. Huebner and William C. Wallen, Ph.D. are Class I directors, whose terms will expire at the next annual meeting following this one;

*Class II directors.* James S. Burns, Peter S. Roddy and Carl Severinghaus are Class II directors, whose terms will expire at the 2014 annual meeting; and

*Class III director and nominee.* John F. Hamilton is a Class III director, whose term will expire upon the election of a new Class III director at the 2012 annual meeting of stockholders (the 2012 Annual Meeting ). John F. Hamilton is not nominated for re-election at the 2012 Annual Meeting and the Board has nominated Roberta L. Della Vedova as the Class III director to fill the board seat currently held by John F. Hamilton.

*Class III Director Nominated for Election to a Three-Year Term Expiring at the 2015 Annual Meeting*

**Roberta L. Della Vedova**, age 59, has served as Vice President of Human Resources and Head of Global Diagnostic Sales at eBioscience, Inc., a global life sciences provider of innovative cell analysis products and technologies, since April 2011. From December 2010 to April 2011, she served as eBioscience's Director of Human Resources and Director of Global Diagnostic Sales. Ms. Vedova co-founded AlliedPath, Inc., a CLIA certified laboratory providing molecular solid tumor testing, and served as its President from June 2008 to November 2010. From February 2006 to June 2008, Ms. Vedova served as Vice President of Human Resources at CovX Research, LLC, a pharmaceutical research and development organization focusing on cancer therapeutics. As the owner of Organization Solutions Group, Inc. from December 2004 to December 2008, she oversaw a training and development franchise that provided services to pharmaceutical, medical device and biotechnology organizations. At Gen-Probe Incorporated, a large medical device organization with products ranging from blood screening to infectious disease diagnostics, Ms. Vedova served as the Vice President of Administration from January 2002 to September 2004, and prior to that as Gen-Probe's Vice President of Human Resources. Ms. Vedova also previously served as Director of Human Resources at Becton Dickinson & Company, a Fortune 500 manufacturer of medical diagnostic equipment and supplies for hospital and laboratories. Ms. Vedova received her B.A. in Business Management from the University of Phoenix and her M.S. in Executive Leadership from the University of San Diego. She also has a lifetime certification as a Senior Professional in Human Resources and is a certified instructor of Zenger-Miller Frontline Leadership.

The Board of Directors believes that Ms. Vedova is qualified to serve as our director as an independent investor representative because she brings a broad range of relevant industry experience to the Board, having previously provided direction and oversight to companies engaged in the development, manufacture, and marketing of bioreagents and instruments, as well as in the delivery of laboratory services for cancer diagnostics.

*Class I Directors Continuing Office until the Next Annual Meeting Following the 2012 Annual Meeting*

**Bruce A Huebner**, age 62, has been our director since May 2011 and serves as the Company's Interim President and Chief Executive Officer on November 26, 2012. Mr. Huebner served as a managing director for LynxCom Partners, LLC, a healthcare consulting firm, from July 2010 through November 2012 and from July





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2008 through September 2009. From October 2009 to June 2010, Mr. Huebner served as President and Chief Executive Officer of TrovaGene, Inc., a developer of molecular diagnostics products based on the detection of transrenal genetic markers. From May 2005 to July 2008, Mr. Huebner served as President of Osmetech Molecular Diagnostics, where he successfully established Osmetech as a fully integrated business, obtaining FDA clearance for four molecular diagnostic microarray products and introducing them to the marketplace. From 2002 to 2004, Mr. Huebner was President and Chief Operating Officer of Nanogen, Inc., a publicly held nanotechnology/microarray company. From 1996 to 2002, Mr. Huebner was Executive Vice President and Chief Operating Officer of Gen-Probe, Inc. which today is one of the world leaders in the development of nucleic acid tests, including a focus on diagnostic tests for infectious disease that affect women's health. Mr. Huebner's other experience includes Vice President of Marketing and Sales at Quidel, Director of Marketing for the U.S. and Director of Marketing and Market Development in Europe for Hybritech, Inc., and various sales and marketing positions at Roche Diagnostics. He currently serves as a director on the board of directors of Pasadena Bioscience Collaborative and Corgenix Medical Corporation. Mr. Huebner received his Bachelor of Science degree in Chemistry from the University of Wisconsin-La Crosse and completed a graduate school senior executive program at Columbia University.

Mr. Huebner's broad experience with various diagnostic companies allows him to assist our Board in evaluating and refining our business strategies and commercial objectives.

**William C. Wallen, Ph.D.**, age 69, has been our director since February 2010 and serves as Chairman of our Nominating and Governance Committee. Additionally, he is a member of our Audit Committee and Compensation Committee, and served on our Scientific Advisory Board from April 2006 until February 2010, when he joined the Board of Directors. Dr. Wallen served as the Senior Vice President and Chief Scientific Officer of IDEXX Laboratories, Inc. (IDEXX) beginning September 2003, and retired from IDEXX on March 3, 2010. Commencing in December 2008, Dr. Wallen took on the position of leading its infectious disease product manufacturing operations. Dr. Wallen led IDEXX's pharmaceutical products business from September 2003 until IDEXX sold certain product lines and restructured that business in 2008. Prior to joining IDEXX, Dr. Wallen held various positions with Bayer Corporation, most recently as Senior Vice President, Research and Development, and Head, Office of Technology for the Diagnostics Division of Bayer Healthcare. From 2001 to 2003, Dr. Wallen served as Senior Vice President and Head of Research, Nucleic Acid Diagnostics Segment; from 1999 to 2001, as Senior Vice President of Research and Development Laboratory Testing Segment; and from 1993 to 1999, as Vice President of Research and Development, Immunodiagnostic and Clinical Chemistry Business Units. Before joining Bayer Corporation, from 1990 to 1993, Dr. Wallen was Vice President, Research and Development at Becton Dickinson Advanced Diagnostics. Dr. Wallen is a member of the American Association of Clinical Chemistry, the American Society for Microbiology, American Association for Cancer Research, The Leukemia Society of America, and the New York Academy of Science. Dr. Wallen has authored or co-authored 55 scientific papers and articles covering topics in immunology, virology, oncology and detection methodologies. Dr. Wallen received his B.S. in Zoology and M.S. in Microbiology from Michigan State University, and Ph.D. in Molecular Biology from University of Arizona College of Medicine.

The Board of Directors has determined that based upon Dr. Wallen's extensive experience in research and development and corporate governance matters in the diagnostics industry, he has the qualifications and skills to serve as a member of our Board of Directors. Dr. Wallen also brings to the Board a background in managing public companies, which gives him the qualification and skills to serve as a key member of the Board's Audit, Compensation, and Nominating and Governance Committees.

*Class II Directors Continuing Office until the 2014 Annual Meeting*

**James S. Burns**, age 66, has been our director since June 2005 and has served as Chairman of the Board since September 29, 2011. Mr. Burns is currently President, Chief Executive Officer and director of AssureRx, Health, Inc., a personalized medicine company which specializes in pharmacogenetics for neuropsychiatric disorders. Prior to joining AssureRx, Health, Inc., Mr. Burns was the President and Chief Executive Officer of

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EntreMed, Inc. from June 2004 to December 2008, and a director from September 2004 to December 2008. Mr. Burns was a co-founder and, from 2001 to 2003, served as President and as Executive Vice President of MedPointe, Inc., a specialty pharmaceutical company that develops, markets and sells branded prescription pharmaceuticals. From 2000 to 2001, Mr. Burns served as a founder and Managing Director of MedPointe Capital Partners, a private equity firm that led a leveraged buyout to form MedPointe Pharmaceuticals. Previously, Mr. Burns was a founder, Chairman, President and Chief Executive Officer of Osiris Therapeutics, Inc., a biotech company developing therapeutic stem cell products for the regeneration of damaged or diseased tissue. Mr. Burns has also been Vice Chairman of HealthCare Investment Corporation and a founding General Partner of Healthcare Ventures L.P., a venture capital partnership specializing in forming companies building around new pharmaceutical and biotechnology products; Group President at Becton Dickinson and Company, a multidivisional biomedical products company; and Vice President and Partner at Booz & Company, Inc., a multinational consulting firm. Mr. Burns is a director of Symmetry Medical Inc. (NYSE: SMA), a supplier of products and services to orthopedic and other medical device companies. Mr. Burns received his B.S. and M.S. in Biological Sciences from the University of Illinois, and M.B.A. from DePaul University. He is a 2012 Board Leadership Fellow of the National Association of Corporate Directors.

Our Board of Directors has determined that based upon Mr. Burns' extensive experience in the diagnostics industry, and current and prior directing and management experience, he has the qualifications and skills to serve as a member of our Board of Directors.

**Peter S. Roddy**, age 53, was appointed to our Board of Directors and Audit Committee on February 18, 2010. Mr. Roddy has served as Vice President and Chief Financial Officer of Pain Therapeutics, Inc. since July 2004, and as its Chief Financial Officer since November 2002. From 1990 to 2002, Mr. Roddy held a variety of senior management positions at COR Therapeutics, Inc. (now part of Takeda Pharmaceutical Company Limited), a biopharmaceutical company, including Senior Vice President, Finance and Chief Financial Officer between 2000 and 2002. Prior to 1990, Mr. Roddy held a variety of positions at Price Waterhouse & Company, Hewlett Packard Company and MCM Laboratories, Inc. Mr. Roddy received his B.S. in Business Administration from the University of California, Berkeley.

Our Board of Directors has determined that based upon Mr. Roddy's extensive experience in the life science industry, including relevant experience as an executive officer and chief financial officer, as well as experience at a major accounting firm, he has the qualifications and skills to serve as a member of our Board of Directors and Chairman of the Audit Committee.

On December 2, 2011, a class action complaint claiming violations of certain securities laws was filed against Pain Therapeutics, Inc. and its executive officers, including Mr. Roddy, in the U.S. District Court for the Western District of Texas by a holder of its securities and its executive officers. This complaint alleged, among other things, violations of Section 10(b), Rule 10b-5, and Section 20(a) of the Exchange Act arising out of allegedly untrue or misleading statements of material facts made by Pain Therapeutics regarding REMOXY during the purported class period from February 3, 2011 to June 23, 2011.

**Carl Severinghaus**, age 60, was appointed to our Board of Directors on March 3, 2010 and serves as our Compensation Committee Chairman. In addition, he is a member of our Audit Committee and also our Nominating and Governance Committee. Since January 1, 2011, Mr. Severinghaus is Vice President, Head Global Sales OEM Components of the Tecan Group. Previously from 2009 until 2011 he was President of Tecan Americas, responsible for Sales and Commercial Operations for the Americas Region, including US, Canada, Central and South America. From 2007 until 2009, he lived in Zurich and was Senior Vice President for International Sales, responsible for Worldwide Sales and Operations. From 1999 to 2007, Mr. Severinghaus was President and General Manager of Tecan US. Prior to becoming President and General Manager, he was Vice President of Sales from 1991 to 1998. Before he joined Tecan he was National Sales Manager for American Monitor Corporation.

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Mr. Severinghaus received his Bachelor of Fine Arts Degree from Drake University in 1974. Mr. Severinghaus is or has been a member of the Analytical & Life Science System Association, Society for Laboratory Automation and Screening (SLAS) and also the American Association of Clinical Chemistry (AACC).

The Board of Directors has determined that based upon Mr. Severinghaus' demonstrated executive level management and commercial operations skills, both domestically and internationally, he has the qualifications and skills to serve as a member of our Board of Directors and a key member of the Board's Audit, Compensation, and Nominating and Governance Committees.

*Class III Director Whose Term Will Expire at the Upcoming Annual Meeting of Stockholders*

**John F. Hamilton**, age 68, has been our director since April 2008. From 1997 until his retirement in 2007, Mr. Hamilton served as Vice President and Chief Financial Officer of Depomed, Inc., a specialty pharmaceutical company focused on enhancing pharmaceutical products. Mr. Hamilton began his career in international banking with The Philadelphia National Bank and Crocker National Bank, and went on to hold senior financial positions at several bio-pharmaceutical companies including Glyko, Inc., which is now BioMarin Pharmaceuticals, and Chiron Corporation. Mr. Hamilton sits on the regional Board of Directors of the Association of Bioscience Financial Officers, and is past-president of the Treasurers Club of San Francisco. Mr. Hamilton received his M.B.A. from the University of Chicago and B.A. in International Relations from the University of Pennsylvania.

Our Board of Directors has determined that based upon Mr. Hamilton's extensive experience in finance and capital markets gained through his education and his senior financial positions at various biopharmaceutical companies, he has the qualifications and skills to serve as a member of our Board of Directors. Mr. Hamilton also brings to the Board significant strategic and financial expertise and leadership experience.

**Information Regarding Executive Officers**

Set forth below is the information about our executive officers in 2012:

Name	Age	Positions
Gail S. Page	57	President and Chief Executive Officer (former)
Bruce A. Huebner	62	Interim President and Chief Executive Officer
Eric J. Schoen	44	Chief Accounting Officer
Donald G. Munroe, Ph.D.	56	Chief Scientific Officer and Vice President of Research and Development (through February 28, 2013); Senior Vice President of Business Development and Chief Scientific Officer (effective March 1, 2013)
William Creech	60	Vice President of Sales and Marketing

*Gail S. Page* joined us in January 2004 as President of our Diagnostics Division and an Executive Vice President, and was promoted to President and Chief Operating Officer of Vermillion in August 2005. Subsequently, Ms. Page became our President and Chief Executive Officer and was named a director in December 2005 and served as President and Chief Executive Officer until her resignation on March 27, 2009 due to our bankruptcy proceeding in 2009. In connection with our emergence from bankruptcy in 2010, Ms. Page was reappointed as our Chief Executive Officer on February 1, 2010. From October 2000 to January 2003, Ms. Page

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was Executive Vice President and Chief Operating Officer of Luminex Corporation. From 1988 to 2000, Ms. Page held various senior level management positions with Laboratory Corporation of America ( LabCorp ). In 1993, Ms. Page was named Senior Vice President, Office of Science and Technology at LabCorp, responsible for the management of scientific affairs in addition to the diagnostics business segment. Additionally, from 1995 to 1997, Ms. Page headed the Cytology and Pathology Services business unit for LabCorp. From 1988 to 2000, Ms. Page was a member of the Scientific Advisory Board at LabCorp and chaired the committee from 1993 to 1997. Prior to her years at LabCorp and its predecessor, Roche Biomedical, Ms. Page worked in various functions in the academic field and the diagnostics industry. Ms. Page received her A.S. in Medical Technology in combination with a Cardiopulmonary Technology Diploma from the University of Florida. Ms. Page also completed an executive management course at the Kellogg School of Management at Northwestern University. On May 15, 2012, we announced Ms. Page's immediate resignation as director, and the mutually agreed termination without cause of Ms. Page as our President and Chief Executive Officer, which was effective December 2, 2012. Ms. Page became a consultant for the Company effective December 3, 2012.

*Bruce A. Huebner* was appointed as the Company's Interim President and Chief Executive Officer on November 26, 2012. Mr. Huebner has been a director of the Company since May 2011 and will continue to serve on the Board. Mr. Huebner most recently served as a managing director for LynxCom Partners, LLC, a healthcare consulting firm. From October 2009 to June 2010, Mr. Huebner served as President and Chief Executive Officer of TrovaGene, Inc., a developer of molecular diagnostics products based on the detection of transrenal genetic markers. From May 2005 to July 2008, Mr. Huebner served as President of Osmetech Molecular Diagnostics, where he successfully established Osmetech as a fully integrated business, obtaining FDA clearance for four molecular diagnostic microarray products and introducing them to the marketplace. From 2002 to 2004, Mr. Huebner was President and Chief Operating Officer of Nanogen, Inc., a publicly held nanotechnology/microarray company. From 1996 to 2002, Mr. Huebner was Executive Vice President and Chief Operating Officer of Gen-Probe, Inc. which today is one of the world leaders in the development of nucleic acid tests, including a focus on diagnostic tests for infectious disease that affect women's health. Mr. Huebner's other experience includes Vice President of Marketing and Sales at Gen-Probe, Vice President of Marketing and Sales at Quidel, Director of Marketing for the U.S. and Director of Marketing and Market Development in Europe for Hybritech, Inc., and various sales and marketing positions at Roche Diagnostics. He currently serves as a director on the board of directors of Pasadena Bioscience Collaborative and Corgenix Medical Corporation. Mr. Huebner received his Bachelor of Science degree in Chemistry from the University of Wisconsin-La Crosse and completed a graduate school senior executive program at Columbia University.

*Eric J. Schoen* joined us in July 2010 as our Corporate Controller. He has been our Chief Accounting Officer since October 2011. Prior to joining us, Mr. Schoen served as Revenue Controller for Borland Software from 2007 to 2010. From 2000 to 2007, he served in Corporate Controller and Director of Finance roles for Trilogy Enterprises, Momentum Software and Alticast, Inc. Mr. Schoen also spent nine years with PricewaterhouseCoopers, most recently as a Manager in the audit and assurance, transaction services and global capital markets practices. Mr. Schoen received his Bachelor of Science in Finance from Santa Clara University.

*Donald G. Munroe, Ph.D.*, joined us in October 2011 as our Chief Scientific Officer and Vice President of Research and Development. Effective March 1, 2013, Dr. Munroe was named our Senior Vice President of Business Development and Chief Scientific Officer. Dr. Munroe has extensive experience in the diagnostic industry, and has been a key member of upper management in a number of prominent diagnostic and life science companies. He served as Vice President, Immunoassay Research and Development from 2009 to 2011 at Beckman Coulter, a preeminent manufacturer of automated diagnostic tests and biomedical instruments. In this role, Dr. Munroe was responsible for launching key Immunoassay menu additions and re-standardizing existing assays. He also initiated manufacturing science investigations and product improvement projects. Previously, Dr. Munroe worked at Invitrogen Corporation in several roles including Vice President, Research and Development (Transplant Diagnostics) from 2006 to 2008, Vice President, Global Program and Portfolio Management (Corporate) from 2004 to 2005, and Director, Research and Development (GIBCO) from 2002 to 2003. Dr. Munroe was Director of Technology Commercialization with Corning (Microarray Technologies) from

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2000 to 2002, and has 10 years of pharmaceutical discovery research experience at R.W. Johnson Pharmaceutical Research Institute (1990 to 1995) and Allelix Biopharmaceuticals (1996 to 2000). Dr. Munroe received his Bachelor of Science in Biology from the University of Guelph, Master of Science in Medical Sciences at McMaster University and Ph.D. in Medical Biophysics at University of Toronto. Dr. Munroe has served as a member of the Scientific Advisory Board of Minneapolis Community & Technical College and is a member of the American Association for Clinical Chemistry and the American Association for the Advancement of Science. Dr. Munroe is an inventor in seven granted U.S. patents, and has authored peer-reviewed publications on the molecular basis of cancer, gastrointestinal disorders, inflammation and other topics.

*William Creech* joined us in March 2010 as Vice President of Sales and Marketing. Prior to joining us, Mr. Creech served as Principal of WBC Consulting, where he provided strategic and tactical consulting services to clients in the medical devices and diagnostics industry from 2008 until March 2010. Mr. Creech has over 30 years of experience in the diagnostics industry, serving as Vice President of Sales and Marketing at Capitol Vial, Inc. from 2005-2008 where he was responsible for creating a sales organization and initiating a scalable pricing program that increased gross margin 500 basis points. He also launched a key new product, Snappies, increasing volume 400% year over year while increasing pricing by 30%. Mr. Creech was Vice President of Corporate Accounts at Apogent Technologies from 1998-2005 where he negotiated multi subsidiary contracts with key customers such as Quest Diagnostics and IDEXX. Prior to that, Mr. Creech was Director of Corporate Accounts at Ciba Corning/Chiron Diagnostics from 1995 to 1998. At Abbott Diagnostics, he served in various sales, sales training and sales management and corporate roles for 14 years from 1981 to 1995, receiving awards such as Presidents Club for 4 straight years and was sales rep of the year for the Diagnostics Division. Mr. Creech served as an Armor officer in the United States Army from 1975 to 1981 and graduated with a B.S. from Florida Southern College.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC and with any national securities exchange on which such securities are traded or quoted. Executive officers, directors and such stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. As a practical matter, we assist our directors and officers by completing and filing Section 16 reports on their behalf. Based solely on a review of the copies of such reports furnished to us, and the written representations of our directors and executive officers, we believe that our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, complied with all applicable filing requirements for the year ended December 31, 2012.

### **Code of Ethics**

We have adopted the Vermillion, Inc. Code of Ethics that applies to all our officers, directors and employees. The Code of Ethics is available under the Investor Relations section of our website at <http://www.vermillion.com>. We will disclose on our website any waiver of, or amendment to, the Code of Ethics.

### **No Change in Director Nomination Process**

As of the date of the filing of this Form 10-K, there have been no material changes to the procedures by which security holders may recommend nominees to our Board of Directors since we previously provided the disclosures required by Item 407(c)(2)(iv) or Item 407 (c)(3) of Regulation S-K.

### **Audit Committee**

The Board of Directors has established an Audit Committee in accordance with section 3(a)(58)(A) of the Exchange Act. The Audit Committee is currently composed of three directors: Mr. Roddy, Chairperson,

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Dr. Wallen and Mr. Severinghaus. The Board has determined that all members of our Audit Committee are independent, as the term is currently defined in NASDAQ Listing Rules 5605(a)(2). The Board has determined that Mr. Roddy qualifies as an audit committee financial expert, as defined in applicable rules. The Board made a qualitative assessment of Mr. Roddy's level of knowledge and experience based on a number of factors, including his experience as the chief financial officer of other companies.

**ITEM 11. EXECUTIVE COMPENSATION**

*Director Compensation*

Outside directors (*i.e.*, non-employee directors) are compensated for their service as (1) a member of the Board of Directors, (2) a member of any committee of the Board of Directors, and (3) a chair of any committee of the Board of Directors. For 2012, we adopted a compensation program granting restricted stock units ( RSUs ) to outside directors with a targeted value on the grant date. The number of RSUs granted is determined by dividing the targeted value by a trailing average price of our common stock on the date of grant of the RSUs. 50% of the RSUs granted to directors vested on June 1, 2012 and 25% of the RSUs vested on each of September 1, 2012 and December 1, 2012, except that 50% of the RSUs granted to John F. Hamilton vested May 15, 2012 and 50% vested on December 13, 2012 due to the fact that Mr. Hamilton was not nominated for re-election at the delayed 2012 Annual Meeting. Outside directors did not receive any cash compensation in connection with their services as directors, nor did they sell any RSUs, except that historically certain RSUs were sold by certain directors only for the purpose of covering their tax liability incurred in connection with the distribution of the RSUs. Periodically, the Compensation Committee reviews and determines the adequacy of the compensation program for outside directors, and based upon the results of their analysis, the Compensation Committee will make recommendations in regards to the compensation program for outside directors to the Board of Directors. During fiscal year 2012, the outside directors were compensated as follows, with the RSU awards being made as of May 15, 2012 based on a grant date value of \$1.99 per RSU:

The chairman of the Board received a total of 35,000 RSUs;

each other outside director received 30,000 RSUs;

the chairperson of the Audit Committee received an additional 6,000 RSUs;

the chairperson of the Compensation Committee received an additional 4,500 RSUs;

the chairperson of the Nominating and Governance Committee received an additional 3,000 RSUs;

the other members of the Compensation Committee each received an additional 2,000 RSUs;

the other members of the Nominating and Governance Committee received an additional 2,000 RSUs; and

the other members of the Audit Committee each received an additional 3,000 RSUs.

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The compensation earned by our outside directors for the year ended December 31, 2012 was as follows:

Name	Fees Earned or Paid in Cash	Stock Awards <sup>(1)</sup>	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
James S. Burns		\$ 69,650	\$	\$	\$	\$	\$ 69,650
John F. Hamilton		51,300					51,300
Peter S. Roddy		71,640					71,640
Carl Severinghaus		78,605					78,605
William C. Wallen, Ph.D.		75,620					75,620
Total	\$	\$ 346,815	\$	\$	\$	\$	\$ 346,815

<sup>(1)</sup> All outside directors received RSUs in lieu of any cash compensation.



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**COMPENSATION COMMITTEE REPORT<sup>1</sup>**

Our executive compensation program for our Named Executive Officers is administered by the Compensation Committee of the Board of Directors. The Compensation Committee has reviewed the Compensation Discussion and Analysis and discussed that analysis with management. Based on its review and discussions with management, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this proxy statement.

This report is provided by the following independent directors of the Compensation Committee:

Carl Severinghaus, Chairman

William C. Wallen

<sup>1</sup> The information provided under the heading Compensation Committee Report shall not be deemed to be soliciting material or filed or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Exchange Act, except to the extent that it is specifically incorporated by reference into a document filed under the Securities Act of 1933, as amended (the Securities Act) or the Exchange Act.

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**COMPENSATION DISCUSSION AND ANALYSIS**

This section describes the compensation program for our Named Executive Officers. In particular, this section focuses on our 2012 compensation program and related decisions. The Compensation Committee annually reviews our executive compensation program to ensure that it appropriately rewards performance that is tied to sound decision-making and creating stockholder value, and is designed to achieve our goals of promoting financial and operational success by attracting, motivating and facilitating the retention of key employees with outstanding talent and ability.

*Named Executive Officers During 2012*

The following executive officers were our Named Executive Officers during 2012.

<b>Name</b>	<b>Positions</b>
Gail S. Page	President and Chief Executive Officer (former)
Bruce A. Huebner	Interim Chief Executive Officer
Donald G. Munroe, Ph.D.	Chief Scientific Officer and Vice President of Research and Development (through February 28, 2013); Senior Vice President of Business Development and Chief Scientific Officer (effective March 1, 2013)
William Creech	Vice President of Sales and Marketing

On May 15, 2012, we announced the mutually agreed termination without cause of Gail S. Page as our President and Chief Executive Officer, which was effective December 2, 2012, after the Company entered into an employment agreement with a successor Chief Executive Officer. Ms. Page became a consultant for the Company effective December 3, 2012.

*Compensation Philosophy and Objectives*

The goal of our compensation program for our Named Executive Officers is the same as for the overall Company, which is to foster compensation policies and practices that attract, engage and motivate high caliber talent by offering compensation in a competitive range. We are committed to a total compensation philosophy and structure that provides flexibility in responding to market factors; rewards and recognizes superior performance; attracts highly skilled, experienced and capable employees; and is fair and fiscally responsible.

The Compensation Committee has designed and implemented compensation programs for Named Executive Officers to reward them for sustaining our financial and operating performance and leadership excellence, to align their interests with those of our stockholders and to encourage them to remain with us for long and productive careers. Because bonus and equity compensation play a key role in aligning our executives' interests with our stockholders' interests, annual incentives and equity incentives constitute an essential portion of the Named Executive Officer compensation. However, most of our compensation elements simultaneously fulfill one or more performance, alignment and/or retention objectives.

Base salary and annual bonus are designed to reward annual achievements and be commensurate with the executive's scope of responsibilities, demonstrated leadership abilities, and management experience and effectiveness. Our other elements of compensation focus on motivating and challenging the executive to achieve superior, longer-term, sustained results.

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In establishing compensation for the Named Executive Officers, the following are the Compensation Committee's objectives:

Attract, retain, reward and motivate high performing executive talent;

Ensure senior officer compensation is aligned with our corporate strategies, business objectives and the long-term interests of our stockholders;

Increase the incentive to achieve key strategic, financial and operational performance measures by linking incentive award opportunities to the achievement of performance goals in these areas;

Ensure that the elements of compensation, individually and in the aggregate, do not encourage excessive risk-taking; and

Enhance the officers' incentive to increase the Company's long term value, as well as promote retention of key people, by providing a portion of total compensation opportunities for senior management in the form of direct ownership in the Company through stock ownership.

The Compensation Committee reviews all components of the Named Executive Officers' compensation, including annual base salary, bonuses based on corporate and individual performance, and equity compensation, perquisites and termination-based compensation. For equity incentive compensation, which includes grants of RSUs and stock options, the Compensation Committee reviews accumulated realized and unrealized stock options and RSU gains. The Compensation Committee also reviews the dollar value to the executive and cost to the Company of all perquisites, as well as the actual and projected payout obligations under several potential severance and change in control scenarios. In addition, from time to time, the Compensation Committee may hire compensation and benefits consultants to assist in developing and reviewing overall executive compensation strategies. The Compensation Committee also receives input from the Chief Executive Officer regarding the compensation of all executives other than the Chief Executive Officer.

On June 6, 2011, we held a stockholder advisory vote on the compensation of our named executive officers, commonly referred to as a say-on-pay vote. Our stockholders approved the compensation of our named executive officers. As we evaluated our compensation practices and talent needs, we were mindful of the strong support our stockholders expressed for our philosophy of linking compensation to our operating objectives and the enhancement of stockholder value. As a result, our compensation committee decided to retain our general approach to executive compensation.

*Compensation Components*

Our executive compensation program is designed to attract executives with the requisite skills necessary to support our strategic objectives, to reward executives for the achievement of near-term and long-term objectives, and to retain executives by aligning compensation with the long-term creation of stockholder value, by developing a sustainable business with consistent performance.

Our compensation program is comprised of the following components for the Named Executive Officers:

Base Salaries;

Annual Incentive Bonus;

Equity Incentives;

Employment Agreements providing for severance and change in control benefits; and

Certain perquisites as well as 401(k) plan, health and welfare plan benefits.

The Compensation Committee believes that these elements of compensation, when combined, are effective, and will continue to be effective, in achieving the overall objectives of our compensation program.

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*Base Salaries.* Executive salaries are determined based on the data from our comparator group, on evaluation of each officer's individual performance throughout the year, level of responsibility, overall salary structure, budget guidelines and assessment of our financial condition. This approach ensures that our cost structure will allow us to remain competitive in the markets. Salaries paid to the Named Executive Officers in fiscal 2012 were within the targeted range. The Compensation Committee normally reviews and adjusts as appropriate the base salaries for the Named Executive Officers in the first half of each calendar year. For fiscal year 2012, **no adjustment of base salary** was made to our existing Named Executive Officers.

*Annual Bonuses.* Consistent with our objectives to tie a significant portion of the Named Executive Officers' total compensation to our performance, all Named Executive Officers have a target bonus of a fixed percentage of their salary. At the beginning of each fiscal year, the Compensation Committee establishes performance measures and goals, which typically include milestones and targets. The Compensation Committee typically assigns a weight value based upon the overall goals in order to ensure a balanced approach to the various factors applied to determining bonus amounts. For fiscal year 2012, these goals, milestones and targets focused primarily on the following:

Continued commercialization of OVA1 and increasing test volume;

Advancing our pipeline;

Broadening reimbursement coverage for OVA1; and

Cash usage and maintaining a strong cash position;

Also, at the beginning of each fiscal year, the Compensation Committee establishes bonus payout targets for each Named Executive Officer. The Compensation Committee generally establishes the individual payout targets for each Named Executive Officer based on the executive's position, level of responsibility and a review of the compensation information of other companies. For 2012, the payout targets for each Named Executive Officer were as follows:

Gail S. Page	50% of annual base salary
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Bruce A. Huebner	\$50,000 annually
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Donald G. Munroe, Ph.D.	40% of annual base salary
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William Creech	40% of annual base salary
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After the close of each fiscal year, or other such timeframe as determined by the Compensation Committee, the Compensation Committee assesses the performance of each Named Executive Officer against the pre-established metrics. Each Named Executive Officer receives a bonus based on his or her individual payout target and our performance relative to the specific performance goal.

In its evaluation of performance for fiscal year 2012, the Compensation Committee considered the following goals, milestones and targets: (i) Continued commercialization of OVA1 and increasing test volume; (ii) Advancing our pipeline; (iii) Broadening reimbursement coverage for OVA1; and (iv) Cash usage and maintaining a strong cash position. As a result of this evaluation, the Compensation Committee determined that the targets for the fiscal year 2012 had partially been met and further, as a cost saving measure and to preserve cash, the Compensation Committee decided that it was in the best interest of the Company to pay actual bonus payouts of approximately 53% of the aggregate bonus target amount for the Named Executive Officers listed below. This resulted in the following payouts to each Named Executive Officer employed by us during such period:

Donald G. Munroe, Ph.D.	\$65,760
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William Creech

\$34,263

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Ms. Page was terminated in 2012 and as such was not entitled to any bonus payments for 2012. Mr. Huebner was named Interim Chief Executive Officer on November 26, 2012 with an annual bonus package of \$50,000. Thus, he was not paid a bonus for 2012.

*Equity Incentive Compensation.* The equity component of our executive compensation program is designed to fulfill our performance alignment and retention objectives. We previously maintained the Vermillion, Inc. 2000 Stock Plan (the "2000 Stock Plan"), which expired in 2010. We will make future equity awards under the 2010 Plan, which was approved by the Board of Directors on February 8, 2010 and by the stockholders on December 3, 2010. The 2010 Plan will be 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, 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, subject to adjustment as provided in the 2010 Plan.

The 2010 Plan generally authorizes us to make awards reserving the following recourse against a participant who does not comply with certain employment-related covenants, either during employment or for certain periods after ceasing to be employed: we may terminate any outstanding, unexercised, unexpired, unpaid, or deferred awards; rescind any exercise, payment or delivery pursuant to the award; or recapture any shares (whether restricted or unrestricted) or proceeds from the participant's sale of shares issued pursuant to the award. These remedies are also generally available to us for awards that would have had a lower grant level, vesting, or payment if a participant's fraud or misconduct had not caused or partially caused the need for a material financial restatement by us or any affiliate. In addition, all awards or proceeds from the sale of awards made or earned pursuant to the 2010 Plan will be subject to the right of us to full recovery (with reasonable interest thereon) in the event that the Board of Directors determines reasonably and in good faith that any participant's fraud or misconduct has caused or partially caused the need for a material restatement of our financial statements for any fiscal year to which the award relates.

In general, the Named Executive Officers receive incentive stock option grants at the time of hire; annually thereafter, they receive additional stock option grants or RSUs, as recommended by the Compensation Committee. Stock option grants and RSUs are based on individual performance and contributions toward the achievement of our business objectives, as well as overall Company performance. The number of underlying shares that may be purchased pursuant to the stock options granted to each Named Executive Officer varies based on the executive's position and responsibilities. In addition, amounts are determined by comparing the level of equity-based compensation that is awarded to executives of competing companies.

The grants of stock-based awards to Named Executive Officers during the year ended December 31, 2012 were as follows:

Name	Restricted Stock Awards:	All Other Option Awards:
	Number of Shares of Stock or Units	Number of Securities Underlying Options
Gail S. Page		150,000
Bruce A. Huebner	34,000 <sup>(1)</sup>	100,000
Donald G. Munroe, Ph.D.		35,000
William Creech		75,000

<sup>(1)</sup> Mr. Huebner was a member of our Board of Directors during all of 2012 and was appointed our Interim Chief Executive Officer on November 26, 2012. The restricted stock grant represented Mr. Huebner's sole compensation as a Board member during 2012. On March 22, 2012, the Compensation Committee granted stock options in lieu of RSUs to executive officers. Certain of such stock options granted to executive officers are subject to a vesting schedule of equal

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vesting over the next 36 months, starting from March 22, 2012. The rest of such options granted to executive officers are subject to a vesting schedule of 100% vesting on March 31, 2013. In addition, the Compensation Committee granted stock options to the interim Chief Executive Officer on November 26, 2012 which are subject to monthly vesting over a one-year period. Such option awards were granted to executive officers as an incentive to create long-term stockholder value and as a retention tool.

*Employee Benefits Programs.* Our employee benefits program primarily consists of two components: (1) severance and change in control arrangements and (2) perquisites and other benefits.

Severance and Change in Control Arrangements. The Compensation Committee believes that executive officers have a greater risk of job loss or modification as a result of a change in control transaction than other employees. Accordingly, our employment agreement with Ms. Page as Chief Executive Officer included change of control provisions, and we have also entered into change in control agreements with our Chief Accounting Officer, Senior Vice President of Business Development and Chief Scientific Officer and Vice President of Sales and Marketing under which they will receive certain payments and benefits upon qualifying terminations that follow a change in control. Our employment agreement with Mr. Huebner as Interim Chief Executive Officer does not contain change of control provisions other than the acceleration of vesting of his stock option grant. The principal purpose of the change in control agreements is to provide executive officers with appropriate incentives to remain with us before, during and after any change in control transaction by providing the executive officers with security in the event their employment is terminated or materially changed following a change in control. By providing this type of security, the change in control agreements help ensure that the executive officers support any potential change in control transaction that may be in the best interests of our stockholders, even while the transaction may create uncertainty in the executive officer's personal employment situation. The Compensation Committee believes that the payment of salary and benefits for one year for Ms. Page as Chief Executive Officer and nine months for the Chief Accounting Officer, Senior Vice President of Business Development and Chief Scientific Officer and Vice President of Sales and Marketing is reasonable and appropriate to achieve the desired objectives of the agreements.

Perquisites and Other Benefits. Our Named Executive Officers participate in our standard employee benefits programs including medical, dental, life, short-term and long-term disability insurance, 401(k) Plan and flexible spending accounts.

*Method for Determining Compensation Amounts*

In deciding on the type and amount of compensation for each executive, the Compensation Committee seeks to align the interests of the Named Executive Officers with those of our stockholders. In making compensation decisions, the Compensation Committee reviews the performance of the company and carefully evaluates an executive's performance during the year against established goals, leadership qualities, operational performance, business responsibilities, career with the company, current compensation arrangements and long-term potential to enhance shareowner value. The types and relative importance of specific financial and other business objectives vary among our Named Executive Officers depending on their positions and the particular operations or functions for which they are responsible. The Compensation Committee does not adhere to rigid formulas when determining the amount and mix of compensation elements. Compensation elements for each executive are reviewed in a manner that optimizes the executive's contribution to the Company, and reflects an evaluation of the compensation paid by our competitors.

The Compensation Committee reviews both current pay and the opportunity for future compensation to achieve an appropriate mix between equity incentive awards and cash payments in order to meet our objectives. However, prior stock compensation gains are not considered in setting future compensation levels. The mix of compensation elements is designed to reward recent results and motivate long-term performance through a combination of cash and equity incentive awards.



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The Compensation Committee has primary responsibility for assisting the Board of Directors in developing and evaluating potential candidates for executive positions, including the Chief Executive Officer, or CEO. As part of this responsibility, the Committee oversees the design, development and implementation of the compensation program for the CEO and the other Named Executive Officers. The Compensation Committee evaluates the performance of the CEO and determines CEO compensation in light of the goals and objectives of the compensation program. The CEO and the Compensation Committee assess the performance of the other Named Executive Officers and determine their compensation, based on initial recommendations from the CEO.

The Compensation Committee approves stock option grants for Named Executive Officers at the time of hire, and thereafter, the Compensation Committee annually reviews and approves stock option or RSU grants. Stock option and RSU grants are based on individual performance and contributions toward the achievement of our business objectives, as well as overall Company performance. Amounts are determined by comparing the level of equity-based compensation awarded to executives of competing companies, along with consideration for attracting, retaining and motivating the executive officers. The stock option and RSU grants made under the 2010 Plan have provisions allowing us to recoup awards if we are required to restate corporate financial statements.

### *Compensation Policies and Practices Regarding Risk Management*

In fulfilling its role in assisting the Board in its risk oversight responsibilities, the Compensation Committee believes that our compensation policies and practices do not motivate imprudent risk taking. Specifically, the Compensation Committee reviewed the following features of our compensation programs that guard against excessive risk-taking:

our annual incentive compensation is based on balanced performance metrics that promote disciplined progress towards longer-term Company goals;

we do not offer significant short-term incentives that might drive high-risk investments at the expense of long-term Company value; and

our compensation awards are capped at reasonable and sustainable levels, as determined by a review of the economic position and prospects, as well as the compensation offered by comparable companies.

### *Tax and Accounting Considerations*

Section 162(m) of the Internal Revenue Code (the Code) disallows a tax deduction to publicly-held companies for certain compensation in excess of \$1,000,000 paid to our chief executive officer and three other officers (other than the chief financial officer) whose compensation is required to be reported to our stockholders pursuant to the Exchange Act. Certain performance-based compensation approved by our stockholders, including option grants under the 2010 Plan, generally is not subject to the deduction limit. It is the Compensation Committee's policy to maximize the effectiveness of our executive compensation in this regard.

We have granted stock options as incentive stock options in accordance with Section 422 of the Code subject to the volume limitations contained in the Code. Generally, the exercise of an incentive stock option does not trigger any recognition of income or gain to the holder. If the stock is held until at least one year after the date of exercise (or two years from the date the option is granted, whichever is later), all of the gain on the sale of the stock, when recognized for income tax purposes, will be capital gain, rather than ordinary income, to the recipient. Consequently, we do not receive a tax deduction. For stock options that do not qualify as incentive stock options, we are entitled to a tax deduction in the year in which the stock options are exercised equal to the spread between the exercise price and the fair market value of the stock for which the stock option was exercised. The holders of the non-qualified stock options are generally taxed on this same amount in the year of exercise.

**Table of Contents***Named Executive Officer Compensation*

*President and Chief Executive Officer.* On December 31, 2005, we entered into an employment agreement with Ms. Page as our President and Chief Executive Officer. Under the terms of her original employment agreement, Ms. Page had an initial base salary of \$350,000, as adjusted by the Board of Directors from time to time; was eligible for a bonus of up to 50% of her base salary that is based on the achievement of reasonable performance-related goals as determined by the Board of Directors; had an initial option grant to purchase 40,000 shares of our common stock at \$9.00 per share; and had an annual car allowance of \$10,000. On November 18, 2008, Ms. Page's employment agreement was amended and restated to reflect an annual base salary of \$364,000 and to comply with (or be exempted from) the applicable requirements of Section 409A of the Code. Ms. Page's employment with us was for an unspecified duration and constituted at-will employment. At the option of either Ms. Page or us, with or without notice, the employment relationship may be terminated at any time, with or without cause (as defined in the employment agreement) or for any or no cause. If we terminate Ms. Page's employment for reasons other than for cause, or if Ms. Page terminates her employment for good reason (as defined in the employment agreement), Ms. Page, upon executing a release of claims in favor of us will be entitled to receive (i) continued payment of base salary for a period of 12 months, (ii) immediate vesting of 24-months of any options previously granted by us in addition to a 24-month period after termination to exercise any or all of her vested options to purchase our common stock; and (iii) continued health and dental benefits paid by us until the earlier of 12 months after termination or the time that Ms. Page obtains employment with reasonably comparable or better health and dental benefits. Additionally, if Ms. Page's employment is terminated by us for reasons other than for cause or by her for good reason within the 12-month period following a change in control (as defined in the employment agreement), Ms. Page will receive (i) continued payment of base salary for a period of 12 months, (ii) immediate 100% vesting of any then unvested options previously granted by us in addition to a period after termination at the discretion of us to exercise any or all of her vested options to purchase our common stock; and (iii) continued health and dental benefits paid by us until the earlier of 12 months after termination or the time that Ms. Page obtains employment with reasonably comparable or better health and dental benefits. Ms. Page's employment agreement also contains a non-solicitation clause, which provides that, in the event that Ms. Page's employment is terminated, she is prohibited from directly or indirectly soliciting or encouraging any employee or contractor of us or our affiliates to terminate employment with or cease providing services to us or our affiliates; and prohibited from soliciting or interfering with any person engaged by us as a collaborator, partner, licensor, licensee, vendor, supplier, customer or client to our detriment. On September 28, 2010, Ms. Page's employment agreement was further amended and restated to increase her annual base salary from \$364,000 to \$385,000.

On May 15, 2012, we announced the mutually agreed termination without cause of Ms. Page as our President and Chief Executive Officer, which was effective as of December 2, 2012, after we entered into an employment agreement with a successor Chief Executive Officer. Due to her mutually agreed termination without cause, pursuant to the terms of her employment agreement and a separation agreement, Ms. Page received (i) a payment equivalent to 12 months of base salary, (ii) upon the effective date of termination, immediate vesting of 24-months of any options and RSUs previously granted by us in addition to a 24-month period after termination to exercise any or all of her vested options to purchase our common stock; and (iii) continued health and dental benefits paid by us until the earlier of 12 months after the effective date of termination or the time that Ms. Page obtains employment with reasonably comparable or better health and dental benefits.

*Interim President and Chief Executive Officer.* On November 26, 2012, we entered into an employment agreement with Mr. Huebner as our Interim President and Chief Executive officer. Pursuant to the terms of the employment agreement, we will pay Mr. Huebner an annual base salary of \$252,000. We will also pay Mr. Huebner a bonus of \$50,000 upon completion of his employment term, which term shall be from November 26, 2012 through the earlier of (i) November 26, 2013, (ii) the Company's hiring of a permanent Chief Executive Officer, or (iii) such other date as determined by the Board. On November 26, 2012, the Board granted Mr. Huebner an option to purchase 100,000 shares of the Company's common stock. The shares subject to the

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option will vest monthly over a twelve (12) month period, provided that 100% of the shares subject to the option will vest immediately upon a change in control of the Company or the Company's hiring of a permanent chief executive officer, subject in each case to his continuing employment with the Company. Mr. Huebner will also be eligible for performance-based stock option grants based on achieving milestones approved by the Board.

*Chief Scientific Officer and Vice President of Research and Development (former); Senior Vice President of Business Development and Chief Scientific Officer (effective March 1, 2013).* On September 23, 2011, we entered into an employment agreement with Donald G. Munroe, Ph.D., effective October 11, 2011. Pursuant to the terms of the employment agreement between the Company and Dr. Munroe, the Company will pay Dr. Munroe an annual base salary of \$250,000. Dr. Munroe will be eligible for a bonus of up to 40% of his base salary for achievement of reasonable performance-related goals and milestones. In the event Dr. Munroe is terminated without cause or resigns for good reason (as these terms are defined in the employment agreement), he is entitled to receive: (i) continued payment of his base salary as then in effect for a period of nine months following the date of termination; and (ii) continued health and dental benefits paid by the Company until the earlier of nine months after termination or the time that Dr. Munroe obtains employment with reasonably comparable or better health and dental benefits. Additionally, if Dr. Munroe's employment is terminated without cause or if he resigns for good reason within the 12-month period following a change of control (as the term is defined in the employment agreement), then, in addition to the severance obligations due to Dr. Munroe as described above, 50% of any then-unvested options previously granted by the Company will vest upon the date of such termination.

*Vice President of Sales and Marketing.* On April 4, 2012, we entered into an employment agreement with William Creech, effective April 4, 2012. Pursuant to the terms of the employment agreement between the Company and Mr. Creech, the Company will pay Mr. Creech an annual base salary of \$225,000. Mr. Creech will be eligible for a bonus of up to 40% of his base salary for achievement of reasonable performance-related goals and milestones. In the event Mr. Creech is terminated without cause or resigns for good reason (as these terms are defined in the employment agreement), he is entitled to receive: (i) continued payment of his base salary as then in effect for a period of nine months following the date of termination; (ii) immediate vesting of 50% of any unvested options previously granted by the Company to him, in addition to a 24-month period after termination to exercise any and all of his vested options to purchase the Company's common stock; and (iii) continued health and dental benefits paid by the Company until the earlier of nine months after termination or the time that Mr. Creech obtains employment with reasonably comparable or better health and dental benefits. Additionally, if Mr. Creech's employment is terminated without cause or if he resigns for good reason within the 12-month period following a change of control (as the term is defined in the employment agreement), then, in addition to the severance obligations due to Mr. Creech as described above, 50% of any then-unvested options previously granted by the Company will vest upon the date of such termination.

**Table of Contents***Compensation for the Named Executive Officers in 2012 and 2011*

The compensation earned by the Named Executive Officers for the years ended December 31, 2012 and 2011 was as follows:

Name and Principal Position	Year	Salary	Bonus	Stock Award <sup>(1)</sup>	Option Awards	Nonqualified Non-Equity Deferred		All Other Compensation <sup>(9)</sup>	Total
						Incentive Plan <sup>(2)</sup>	Earnings Compensation <sup>(9)</sup>		
Gail S. Page	2012	\$ 352,917	\$	\$ 258,884	\$ 168,837	\$	\$	\$ 508,855 <sup>(4)</sup>	\$ 1,289,493
President and Chief Executive Officer (former)	2011	385,000		1,085,946 <sup>(3)</sup>	76,726	57,750		22,281 <sup>(4)</sup>	1,627,703
Bruce A. Huebner	2012	25,846		67,660 <sup>(5)</sup>	7,869			4,800 <sup>(6)</sup>	106,175
Director and Interim Chief Executive Officer	2011			26,491 <sup>(5)</sup>				9,200 <sup>(6)</sup>	35,691
Donald G. Munroe, Ph.D.	2012	250,000			61,802	65,760		572	378,134
Chief Scientific Officer and VP of Research and Development <sup>(10)</sup>	2011	55,929			7,426	6,740		30,095 <sup>(7)</sup>	100,190
William Creech	2012	225,000		27,533	80,981	34,263		7,127 <sup>(8)</sup>	374,904
Vice President of Sales and Marketing	2011	214,236		21,686	56,705	27,000		7,400 <sup>(8)</sup>	327,027

<sup>(1)</sup> Represents non-cash, equity-related compensation. More information regarding these awards is included in the Compensation Discussion and Analysis as well as in Note 8 to our Annual Report on Form 10-K for the year ended December 31, 2012.

<sup>(2)</sup> Amount represents performance bonus for fiscal year 2012 and 2011.

<sup>(3)</sup> Includes non-cash, equity-related compensation determined as of the date of grant for restricted stock awards pursuant to the Debtor's Incentive Plan and included in the Company's financial statements for 2011. In 2011, includes \$993,780 from Debtor's Incentive Plan and \$92,166 for 2011 Restricted Stock Awards.

<sup>(4)</sup> In 2012, represents \$385,000 severance payment, \$51,825 PTO payout, \$18,000 consulting fees, \$17,100 post-employment benefit payments, tax gross-up on stock awards of \$36,406 and \$524 for insurance premiums. In 2011, represents tax gross-up payments on stock awards of \$21,709 and \$572 for insurance premiums.

<sup>(5)</sup> Represents Mr. Huebner's compensation as a member of our Board of Directors for 2012 (prior to his appointment as Chief Executive Officer on November 26, 2012) and 2011.

<sup>(6)</sup> Represents Mr. Huebner's consulting income prior to his appointment as Chief Executive Officer on November 26, 2012.

<sup>(7)</sup> Includes one-time payment of relocation assistance of \$30,000.

<sup>(8)</sup> Includes Mr. Creech's car allowance of \$6,600 in 2012 and \$6,900 in 2011.

<sup>(9)</sup> All Other Compensation also includes Company paid insurance premiums of less than \$1,000.

<sup>(10)</sup> Effective March 1, 2013, Dr. Munroe was named our Senior Vice President of Business Development and Chief Scientific Officer.

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The outstanding equity awards held by the Named Executive Officers as of December 31, 2012, were as follows:

Name	Option Awards					Stock Awards				
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unearned Options	Option Exercise Price	Option Expiration Date <sup>(1)</sup>	Number of Shares or Units of Stock that have not Vested	Market Value of Shares or Units of Stock that have not Vested <sup>(2)</sup>	Unearned Shares, Units or Other Rights that have not Vested	Unearned Shares, Units or Other Rights that have not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that have not Vested
Gail S. Page	138,888			1.62	12/2/2014					
	125,000			2.30	12/2/2014					
	35,999			14.70	12/2/2014					
	25,000			12.00	12/2/2014					
	39,999			9.00	12/2/2014					
	12,500			21.90	12/2/2014					
	9,999			29.60	12/2/2014					
Bruce A. Huebner	8,333	91,667		1.19	11/25/2022					
Donald G. Munroe, Ph.D.	2,500	32,500		1.62	3/21/2022					
	36,458	88,542		1.96	11/7/2021					
William Creech	12,500	62,500		1.62	3/21/2022	8,334	11,001			
	6,873	3,127		28.65	3/18/2020					

<sup>(1)</sup> Stock options vest ratably on a monthly basis either over 12 or 36 month period, commencing on the date of the grant, or over four years as follows: 25% of the shares vest one year following the vesting commencement date, with the remaining 75% vesting in equal monthly installments over the next three years. In addition, certain option grants cliff vest after a one year period from grant date. Each option expires 10 years after the date of the grant or, in the case of an incentive stock option, such shorter term as may be provided in the applicable agreement.

<sup>(2)</sup> The fair value of our common stock as of December 31, 2012 was \$1.32 per share.

**Table of Contents***Potential Payments Upon Termination*

A severance payment of \$385,000 and benefits totaling \$17,100 became payable to Gail S. Page upon her termination in December 2012. The following table set forth amounts payable to the other Named Executive Officers should an officer be terminated as of December 31, 2012:

Name	Termination Scenario	Continued Payment of Base Salary	Non-Equity Incentive Payout	Immediate Vesting of Stock Options <sup>(3)</sup>	Health and Dental Insurance Benefits <sup>(4)</sup>
Bruce A. Huebner <sup>(5)</sup>	Termination <sup>(1)</sup>	\$	\$ 50,000	\$ 11,917	\$
	Within 12 Months After Change-in Control <sup>(2)</sup>		50,000	11,917	
	For cause				
Donald G. Munroe, Ph.D.	Termination <sup>(1)</sup>	187,500			20,005
	Within 12 Months After Change-in Control <sup>(2)</sup>	187,500			20,005
	For cause				
William Creech	Termination <sup>(1)</sup>	168,750			13,905
	Within 12 Months After Change-in Control <sup>(2)</sup>	168,750			13,905
	For cause				

(1) Termination includes the following separation scenarios: involuntary termination not for cause or resignation for good reason (in all cases, assuming the executive is not entering into competitive or other activity detrimental to us).

(2) Termination of employment by us for reasons other than for cause or by Named Executive Officers for good reason within the 12-month period following a change in control (as defined in the respective employment agreements).

(3) Assumes each Named Executive Officer exercised all vested, in-the-money options at \$1.32 (the December 31, 2012 closing price of our common stock). These amounts are in addition to the existing value of options vested at December 31, 2012.

(4) Assumes each Named Executive Officer does not obtain employment with reasonably comparable or better health and dental benefits within the time period specified in the respective employment agreements.

**Table of Contents****ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

See the description regarding our equity compensation plans contained in Item 5 of this Form 10-K and in the notes to our financial statements, attached hereto.

**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information known to us regarding beneficial ownership of our common stock as of December 31, 2012, by (1) each person known by us to be the beneficial owner of five percent or more of the outstanding shares of the common stock, (2) each director as of December 31, 2012, (3) each Named Executive Officer as of December 31, 2012, and (4) all directors and executive officers as of December 31, 2012 as a group. All shares are subject to the named person's sole voting and investment power except where otherwise indicated. Unless otherwise noted below, the address of each beneficial owner listed in the table is c/o Vermillion, Inc., 12117 Bee Caves Road, Building Three, Suite 100, Austin, TX 78738.

Beneficial ownership is determined in accordance with Rule 13d-3(d)(1) under the Exchange Act. Shares of common stock, which are issued and outstanding, are deemed to be beneficially owned by any person who has or shares voting or investment power with respect to such shares. Shares of common stock which are issuable upon exercise of options or warrants are deemed to be issued and outstanding and beneficially owned by any person who has or shares voting or investment power over such shares only if the options or warrants in question are exercisable within 60 days of December 31, 2012, and, in any event, solely for purposes of calculating that person's percentage ownership of the common stock (and not for purposes of calculating the percentage ownership of any other person).

The number of shares of common stock deemed outstanding and used in the denominator for determining percentage ownership for each person equals (i) 15,200,079 shares of common stock outstanding as of December 31, 2012, plus (ii) such number of shares of common stock as are issuable pursuant to RSUs, options, warrants or convertible securities held by that person (and excluding RSUs, options, warrants and convertible securities held by other persons) which may be exercised within 60 days of December 31, 2012.

Name and Address of Beneficial Owner	Number of Common Stock Shares Beneficially Owned	Percentage of Outstanding Shares Beneficially Owned
<b>Beneficial Owners more than 5%:</b>		
Quest Diagnostics Incorporated <sup>(1)</sup> 1290 Wall Street West Lyndhurst, NJ 07071	860,595	5.66%
<b>Directors and Named Executive Officers:</b>		
James S. Burns <sup>(2)</sup>	164,108	1.08%
John F. Hamilton <sup>(3)</sup>	148,708	*
Bruce A. Huebner <sup>(4)</sup>	99,426	*
Peter S. Roddy	69,700	*
Carl Severinghaus	67,000	*
Roberta L. Della Vedova (Nominee)		*
William C. Wallen, Ph.D.	79,200	*
Gail S. Page <sup>(5)</sup> (Former President and Chief Executive Officer)	612,292	3.93%
Donald G. Munroe, Ph.D. <sup>(6)</sup>	44,721	*
William Creech <sup>(7)</sup>	44,313	*
<b>All Directors and Executive Officers as a Group (11 persons)<sup>(8)</sup></b>	<b>1,378,401</b>	<b>8.74%</b>



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- \* Less than 1%.
- (1) Quest Diagnostics Incorporated is a publicly-held company. Quest Diagnostics Incorporated's executive officers are responsible for running the business of the company and thus, exercise voting and investment control over the shares owned by Quest Diagnostics Incorporated.
- (2) Includes 40,400 shares issuable upon exercise of options exercisable within 60 days of December 31, 2012.
- (3) Includes 30,000 shares issuable upon exercise of options exercisable within 60 days of December 31, 2012.
- (4) Includes 24,999 shares issuable upon exercise of options exercisable within 60 days of December 31, 2012.
- (5) Includes 387,385 shares issuable upon exercise of options exercisable within 60 days of December 31, 2012.
- (6) Dr. Munroe is our Chief Scientific Officer and Vice President of Research and Development. Effective March 1, 2013, Dr. Munroe was named our Senior Vice President of Business Development and Chief Scientific Officer. Amount represents shares issuable upon exercise of options exercisable within 60 days of December 31, 2012.
- (7) Includes 24,232 shares issuable upon exercise of options exercisable within 60 days of December 31, 2012.
- (8) The group includes James S. Burns, John F. Hamilton, Bruce A. Huebner, Gail S. Page, Peter S. Roddy, Carl Severinghaus, Roberta L. Della Vedova, William C. Wallen, Ph.D., Eric J. Schoen, Donald G. Munroe and William Creech.

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

**Transactions with Related Persons**

For the years ended December 31, 2012, we did not engage in nor are we currently proposed to engage in any transaction or series of similar transactions to which we were or are to be a party in which the amount involved exceeds \$120,000 and in which any director, executive officer, holder of more than 5% of our common stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest other than (1) compensation agreements and other arrangements, which are described in Executive Compensation, and (2) the transactions described below.

*Relationship with Quest Diagnostics Incorporated*

Quest Diagnostics Incorporated ( Quest Diagnostics ) is a significant stockholder of Vermillion. 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 amended to expire on the earlier of (i) October 7, 2012 and (ii) the date on which Quest Diagnostics made its third development election. Quest Diagnostics has selected two diagnostic tests to commercialize, a peripheral arterial disease blood test and OVA1, prior to the October 7, 2012 expiration of the Strategic Alliance. Pursuant to the Amended Strategic Alliance Agreement, Quest Diagnostics will have the non-exclusive right to commercialize each of these tests on a worldwide basis, with exclusive commercialization rights in the clinical reference lab marketplace in each restricted territory, as the 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 United States Food and Drug Administration ( FDA ). As part of the Strategic

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Alliance, there is a royalty arrangement under which Quest Diagnostics will pay royalties to us based on fees earned by Quest Diagnostics for applicable diagnostic services, and we will pay royalties to Quest Diagnostics based on our revenue from applicable diagnostic products. On November 10, 2010, we entered into Amendment No. 4 to the Strategic Alliance Agreement with Quest Diagnostics. Pursuant to this Amendment, Quest Diagnostics will have the exclusive right to commercialize OVA1 for up to three additional years from the period as specified in the Strategic Alliance

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

### *Directors and Executive Officers*

On June 17, 2011, we entered into a consulting agreement with Bruce A. Huebner, a member of our Board of Directors. Pursuant to the terms of the consulting agreement, Mr. Huebner provided consulting services regarding sales, marketing, business development and corporate strategy and was paid \$200 per hour. For the year ended December 31, 2012 and 2011, the total amount of consulting fee expense for Mr. Huebner was \$5,000 and \$9,000, respectively. On November 27, 2012, we announced the appointment of Mr. Huebner as Interim Chief Executive Officer. Mr. Huebner continues to serve on our Board of Directors.

On December 3, 2012, we entered into a consulting agreement with our former President and Chief Executive Officer and director, Gail S. Page. Pursuant to the terms of the consulting agreement, Ms. Page will assist the Company as needed, including providing advice and recommendations with respect to the development and commercialization of the Company's existing and future diagnostic tests, and managing and developing relationships with existing and future collaborators and partners. She will provide a minimum of 48 and a maximum of 96 hours of consulting services per month. In consideration for such services, we will pay Ms. Page a monthly fee of \$18,000, plus \$250 for each hour of services provided in excess of the 48 hour minimum. The Consulting Agreement has an initial term of six months, after which it may be renewed for an additional six month term by mutual agreement of the Company and Ms. Page. For the year ended December 31, 2012, the total amount of consulting fee expense to Ms. Page was \$18,000. The consulting agreement has been terminated with an effective date of March 15, 2013.

In November 2011, we entered into a consulting agreement with our former Senior Vice President and Chief Science Officer, Eric T. Fung, M.D., Ph.D.. Pursuant to the terms of the consulting agreement, Dr. Fung served as our Chief Medical Officer and a member of our Scientific Advisory Board. Dr. Fung's consulting agreement and Scientific Advisory Board services were terminated in June 2012. For the year ended December 31, 2012 and 2011, the total amount of consulting fee expense for Dr. Fung was \$27,000 and \$6,000, respectively. During 2012, Dr. Fung also continued to vest in restricted stock with a fair value of \$11,000 until the termination of the consulting agreement.

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 provided consulting services. This consulting agreement was terminated in June 2012. For the year ended December 31, 2012, the total amount of consulting fee expense to our former Vice President of Strategy was \$23,000 and the fair value of continued vesting in restricted stock was \$1,000 until the termination of the consulting agreement.

We have entered into indemnification agreements with each of our directors and executive officers, which require us to indemnify our directors and officers to the fullest extent permitted by law in the State of Delaware.

### **Review and Approval of Transactions with Related Persons**

Our written corporate governance guidelines require all members of the Board of Directors to inform the Audit Committee of the Board of Directors of all types of transactions between themselves (directly or indirectly) and the Company, prior to their conclusion, even if such transactions are in the ordinary course of business. The Audit Committee reviews and approves all related party transactions for which Audit Committee approval is required by NASDAQ Listing Rules and other applicable laws. The guidelines also provide that the Board of Directors should ensure that there is no abuse of corporate assets or unlawful related party transactions. Our corporate governance guidelines are posted under the Investor Relations section of our website at <http://www.vermillion.com>.

**Table of Contents****Independence of the Board of Directors and Nominee**

After a review of all relevant transactions or relationships between each director and our recommended nominee for election, or any of his family members, on the one hand, and the Company, our senior management and its independent registered public accounting firm, on the other hand, the Board has affirmatively determined that our recommended nominee for election, and all of our directors other than Mr. Huebner (by virtue of his recent appointment as our Interim Chief Executive Officer) are, or, in the case of our recommended nominee, would be if elected, independent directors, as the term is currently defined under NASDAQ Listing Rule 5605(a)(2).

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES****Audit Fees and Non-Audit Fees**

On April 4, 2012, the Audit Committee of the Board selected BDO USA, LLP to serve as our independent registered public accounting firm. BDO USA, LLP has represented to us that it is independent with respect to the Company within the meaning of the published rules and regulations of the SEC. Prior to April 4, 2012, PricewaterhouseCoopers LLP served as our independent registered public accounting firm.

The following is a summary of the fees and services provided by BDO USA, LLP for fiscal year 2012 and PricewaterhouseCoopers LLP for fiscal year 2011.

	2012	2011
Audit fees	\$ 146,412	\$ 298,786
Audit-related fees		
Tax fees	31,952 <sup>(2)</sup>	
All other fees <sup>(1) (3)</sup>	15,107	25,971
<b>Total</b>	<b>\$ 193,471</b>	<b>\$ 324,757</b>

<sup>(1)</sup> Includes \$12,497 of fees paid in 2012 for preparation of the 2011 income tax provision and services provided prior to BDO USA, LLP being named our independent registered public accounting firm.

<sup>(2)</sup> Represents \$23,012 in fees for the preparation of our 2011 federal and state tax returns and \$8,940 for a loss limitation study under IRC Section 382 as of December 31, 2011.

<sup>(3)</sup> All other fees in 2012 included \$2,610 for consulting services regarding the liquidation of our Japanese subsidiary. All other fees in 2011 related to the review of our secondary offering filing on Form S-1 and miscellaneous other expenses.

**Audit Committee Pre-Approval of Policies and Procedures**

The Audit Committee is responsible for appointing, compensating and overseeing the work of the independent registered public accounting firm. The Audit Committee has established a pre-approval procedure for all audit and permissible non-audit services to be performed by our independent registered public accounting firm. The pre-approval policy requires that requests for services by the independent registered public accounting firm be submitted to our Chief Accounting Officer for review and approval. Any requests that are approved by the Chief Accounting Officer are then aggregated and submitted to the Audit Committee for approval at a meeting of the Audit Committee. Requests may be made with respect to either specific services or a type of service for predictable or recurring services.

All audit, audit-related, tax and other services, which include all permissible non-audit services, provided to us by BDO USA, LLP and PricewaterhouseCoopers LLP were pre-approved by the Audit Committee. Additionally, the Audit Committee concluded that the provision of those services by BDO USA, LLP and PricewaterhouseCoopers LLP was compatible with the maintenance of the independent registered public

accounting firm's independence.

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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-27.

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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**VERMILLION, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page No.</b>
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<u>Consolidated Balance Sheets at December 31, 2012 and 2011</u>	F-3
<u>Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2012 and 2011</u>	F-4
<u>Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2012 and 2011</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2012 and 2011</u>	F-6
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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders

Vermillion, Inc.

Austin, Texas

We have audited the accompanying consolidated balance sheet of Vermillion, Inc. ( Company ) as of December 31, 2012 and the related consolidated statement of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended. 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 audit.

We conducted our audit 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Vermillion, Inc. at December 31, 2012, and the results of its operations and its cash flows for the year ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated 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 suffered recurring losses and negative cash flows from operations and has an accumulated deficit, 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Austin, Texas

March 1, 2013

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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 the results of their operations and their cash flows for the year 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 audit. We conducted our audit 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 audit provides a reasonable basis for our opinion.

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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**Table of Contents****Vermillion, Inc.****Consolidated Balance Sheets**

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

	December 31,	
	2012	2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,007	\$ 22,477
Accounts receivable	137	99
Prepaid expenses and other current assets	348	317
Total current assets	8,492	22,893
Property and equipment, net	142	216
Other assets		2
Total assets	\$ 8,634	\$ 23,111
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 525	\$ 1,331
Accrued liabilities	1,074	2,592
Short-term debt	1,106	7,000
Deferred revenue	492	553
Total current liabilities	3,197	11,476
Non-current liabilities:		
Long-term deferred revenue	770	1,224
Other liabilities		52
Total liabilities	3,967	12,752
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2012 and 2011		
Common stock, \$0.001 par value, 150,000,000 shares authorized; 15,200,079 and 14,900,831 shares issued and outstanding at December 31, 2012 and 2011, respectively	15	15
Additional paid-in capital	328,097	326,796
Accumulated deficit	(323,445)	(316,299)
Accumulated other comprehensive loss		(153)
Total stockholders' equity	4,667	10,359
Total liabilities and stockholders' equity	\$ 8,634	\$ 23,111

See accompanying Notes to Consolidated Financial Statements



**Table of Contents****Vermillion, Inc.****Consolidated Statements of Operations and Comprehensive Loss**

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

	Year Ended December 31,	
	2012	2011
<b>Revenue:</b>		
Product	\$ 1,640	\$ 1,469
License	454	454
<b>Total revenue</b>	<b>2,094</b>	<b>1,923</b>
<b>Cost of revenue:</b>		
Product	131	129
<b>Total cost of revenue</b>	<b>131</b>	<b>129</b>
<b>Gross profit</b>	<b>1,963</b>	<b>1,794</b>
<b>Operating expenses:</b>		
Research and development <sup>(1)</sup>	2,216	5,387
Sales and marketing <sup>(2)</sup>	4,653	5,539
General and administrative <sup>(3)</sup>	4,508	8,509
<b>Total operating expenses</b>	<b>11,377</b>	<b>19,435</b>
Loss from operations	(9,414)	(17,641)
Interest income	28	64
Interest expense	(206)	(396)
Gain on sale of instrument business	1,830	
Gain on litigation settlement, net	710	
Change in fair value of warrants		378
Reorganization items	88	(96)
Other expense, net	(182)	(99)
Loss before income taxes	(7,146)	(17,790)
Income tax benefit (expense)		
<b>Net loss</b>	<b>\$ (7,146)</b>	<b>\$ (17,790)</b>
<b>Net loss per share basic and diluted</b>	<b>\$ (0.48)</b>	<b>\$ (1.25)</b>
Weighted average common shares used to compute basic and diluted net loss per common share	15,010,868	14,249,570
<b>Net loss</b>	<b>\$ (7,146)</b>	<b>\$ (17,790)</b>
Foreign currency translation adjustment	153	3
<b>Comprehensive loss</b>	<b>\$ (6,993)</b>	<b>\$ (17,787)</b>
<b>Non-cash stock-based compensation expense included in operating expenses:</b>		
(1) Research and development	\$ 127	\$ 686
(2) Sales and marketing	203	158
(3) General and administrative	965	2,446

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See accompanying Notes to Consolidated Financial Statements

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**Table of Contents****Vermillion, Inc.****Consolidated Statements of Changes in Stockholders' Equity**

(Amounts in Thousands, Except Share Amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2010</b>	10,657,564	11	303,270	(298,509)	(156)	4,616
Net loss				(17,790)		(17,790)
Foreign currency translation adjustment					3	3
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 conjunction with exercise 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
<b>Balance at December 31, 2011</b>	14,900,831	15	326,796	(316,299)	(153)	10,359
Net loss				(7,146)		(7,146)
Foreign currency translation adjustment					153	153
Common stock issued in conjunction with exercise of stock options	8,333		6			6
Common stock issued for restricted stock awards	290,915		715			715
Warrants issued for services			14			14
Stock compensation charge			566			566
<b>Balance at December 31, 2012</b>	15,200,079	\$ 15	\$ 328,097	\$ (323,445)	\$	\$ 4,667

See accompanying Notes to Consolidated Financial Statements

**Table of Contents****Vermillion, Inc.****Consolidated Statements of Cash Flows**

(Amounts in Thousands)

	<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,146)	\$ (17,790)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrants		(378)
Foreign currency loss on liquidation	153	
Non-cash license revenue	(454)	(454)
Loss on sale and disposal of property and equipment	2	
Depreciation and amortization	86	77
Stock-based compensation expense	1,281	3,286
Warrants issued for services	14	4
Gain from sale of instrument business to Bio-Rad	(1,830)	
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	(38)	37
Decrease (increase) in prepaid expenses and other current assets	(31)	462
Decrease in other assets	2	10
Increase (decrease) in accounts payable and accrued liabilities	(2,292)	253
Decrease in deferred revenue	(61)	(497)
Decrease in other liabilities	(52)	(207)
Reorganization items	(32)	(384)
Net cash used in operating activities	(10,398)	(15,581)
<b>Cash flows from investing activities:</b>		
Proceeds from the sale of instrument business to Bio-Rad	1,830	
Purchase of property and equipment	(14)	(99)
Net cash provided by / (used in) investing activities	1,816	(99)
<b>Cash flows from financing activities:</b>		
Principal repayment of short-term debt	(5,894)	
Principal repayment of 7.00% convertible senior notes		(5,000)
Proceeds from sale of common stock, net of issuance costs		20,206
Proceeds from issuance of common stock from exercise of stock options	6	34
Net cash (used in) / provided by financing activities	(5,888)	15,240
Effect of exchange rate changes on cash and cash equivalents		3
Net decrease in cash and cash equivalents	(14,470)	(437)
Cash and cash equivalents, beginning of year	22,477	22,914
Cash and cash equivalents, end of year	\$ 8,007	\$ 22,477

**Supplemental disclosure of cash flow information:**

**Cash paid during the period for:**

Interest	\$	227	\$	462
Income taxes				

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 3, we distribute OVA1 through Quest Diagnostics, which has the non-exclusive right to commercialize OVA1 on a worldwide basis, with exclusive commercialization rights in the clinical reference lab marketplace 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 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 OvaCheck2 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. We paid \$5,000,000 in September 2011 to repay the 7.00% Notes. We paid \$5,894,000 in October 2012 to repay the Secured Line of Credit with Quest Diagnostics.

We have incurred significant net losses and negative cash flows from operations since inception. At December 31, 2012, we had an accumulated deficit of \$323,445,000 and stockholders equity of \$4,667,000. On December 31, 2012, we had \$8,007,000 of cash and cash equivalents and \$3,197,000 of current liabilities.

We expect cash for OVA1 from Quest Diagnostics to be our only material, recurring source of cash in 2013. 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 may seek to raise capital through a variety of sources, including the public equity market, private equity financing, collaborative arrangements, licensing arrangements, and/or public or private debt.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. 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.

### ***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.

### ***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:

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 our cash and cash equivalents in recognized financial institutions in the United States. 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.

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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, 2012 and 2011 and revenues for the years then ended are from one 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 \$137,000 and \$85,000 at December 31, 2012 and 2011, respectively.

***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 3). 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 sufficient 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. Through December 31, 2012, 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.

### ***Patent Costs***

Costs incurred in filing, prosecuting and maintaining patents (principally legal fees) are expensed as incurred and recorded within selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss. Such costs aggregated approximately \$312,000 and \$363,000 for the years ended December 31, 2012 and 2011, respectively.

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***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.

***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.

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 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. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, and disclosure.

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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. CIPHERGEN Biosystems KK was liquidated during 2012 and, consequently, the accumulated other comprehensive loss totaling \$153,000 was recognized in the consolidated statement of operations for 2012 and included in Other Expense in the consolidated statements of operations and comprehensive loss.

### ***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 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, accounts receivable, accounts payable, accrued liabilities and short-term debt. 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, accrued liabilities and short-term debt are at cost, which approximates fair value due to the short maturity of those instruments.

### ***Segment Reporting***

We operate one reportable segment, novel diagnostic tests.

### **NOTE 2: RECENT 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 adopted this pronouncement in the first quarter of 2012, and it had no effect on our financial position, results of operations or cash flows but did impact the way we present comprehensive income.

**Table of Contents****NOTE 3: 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 amended to expire on the earlier of (i) October 7, 2012 and (ii) the date on which Quest Diagnostics makes its third development election. We further amended the Strategic Alliance Agreement to give Quest Diagnostics the exclusive right to commercialize OVA1 for two additional years to September 2014, 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. Quest Diagnostics has selected two diagnostic tests to commercialize, a peripheral arterial disease blood test and OVA1.

***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. 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, 2012 and 2011. This secured line of credit also contains provisions for Quest Diagnostics to forgive portions of the amounts borrowed that correspond to our achievement of certain milestones related to development, regulatory approval and commercialization of certain diagnostic tests. The amounts to be forgiven and the corresponding milestones 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.

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

The outstanding principal balance of this secured line of credit was \$1,106,000 and \$7,000,000 at December 31, 2012 and 2011, respectively. Interest expense related to this secured line of credit was \$206,000 and \$263,000 for the years ended December 31, 2012 and 2011, respectively. 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 we were no longer in default under the terms of the secured line of credit while under Chapter 11 bankruptcy protection. In January 2010, we cured the default and the principal balance was reduced to \$7,000,000.

We also believe we achieved the milestone for an application that allows a licensed laboratory test to be commercialized when OVA1 was cleared by the FDA in September 2009 and the secured line of credit is expected to be reduced by an additional \$1,000,000 resulting in outstanding principal of \$6,000,000. However, Quest Diagnostics has disputed that the milestone has been met.

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

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On October 12, 2012, we paid Quest Diagnostics approximately \$5,894,000 of principal and \$7,000 of accrued interest which we believe represents payment in full of all outstanding principal and interest under the secured line of credit. We continue to show the amount of the liability as \$1,106,000 as of December 31, 2012 given that Quest Diagnostics has disputed that the \$1,000,000 milestone was met.

**NOTE 4: PROPERTY AND EQUIPMENT**

The components of property and equipment as of December 31, 2012 and 2011 were as follows:

(in thousands)	December 31,	
	2012	2011
Machinery and equipment	\$ 193	\$ 184
Demonstration equipment	33	30
Computer equipment and software	114	251
Furniture and fixtures	65	65
<b>Gross property and equipment</b>	<b>405</b>	<b>530</b>
Accumulated depreciation and amortization	(263)	(314)
<b>Property and equipment, net</b>	<b>\$ 142</b>	<b>\$ 216</b>

Depreciation expense for property and equipment was \$86,000 and \$77,000 for the years ended December 31, 2012 and 2011, respectively.

**NOTE 5: ACCRUED LIABILITIES**

The components of accrued liabilities as of December 31, 2012 and 2011 were as follows:

(in thousands)	December 31,	
	2012	2011
Payroll and benefits related expenses	\$ 464	\$ 641
Collaboration and research agreements expenses	133	303
Professional services	236	279
Contingencies (See Note 9)		1,025
Tax-related liabilities	17	76
Other accrued liabilities	224	268
<b>Total accrued liabilities</b>	<b>\$ 1,074</b>	<b>\$ 2,592</b>

**NOTE 6: 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. The 7.00% Notes were sold pursuant to separate exchange and redemption agreements between Vermillion and holders of the then 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. The 7.00% Notes were 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





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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 if the closing price of the stock equaled or exceeded 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.

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.

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 in January 2010. In September 2011, \$5,000,000 in aggregate principal amount of the 7.00% Notes remained outstanding and was repaid in full.

***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 in September 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 holder into shares of our common stock initially at a conversion rate of 10.88 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.

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 in September 2008. Interest of \$56,000 related to the 4.50% Notes was paid in September 2008. Subsequently in December 2008, 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.

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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 in 2010, 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 in January 2010 settled the 4.50% Notes in full.

**NOTE 7: COMMITMENTS AND CONTINGENCIES*****Operating Leases***

We lease 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. The original 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. This lease was amended on the same terms to May 31, 2014.

Rental expense under operating leases for the years ended December 31, 2012 and 2011 totaled \$110,000 and \$129,000, respectively.

As of December 31, 2012, including the extension of our Austin, TX facility operating lease in January 2013, future minimum rental payments under noncancelable operating leases were \$94,000 and \$39,000 for the years ending December 31, 2013 and 2014, 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. In January 2013, we further amended the collaboration agreement extending the term to March 31, 2016 and requiring payments of \$400,000 in 2013 and \$100,000 in 2014. Collaboration expenses under the JHU collaboration were \$251,000 and \$235,000 for the years ended December 31, 2012 and 2011, 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 \$57,500. As of December 31, 2012 and 2011, we owed none and \$4,000 related to research collaboration agreements with JHU, respectively.

***Gain on Litigation Settlement***

On February 9, 2012, we entered into a Settlement Agreement with Oppenheimer & Co., Inc. ( Oppenheimer ) related to losses on our short and long-term investments in previous years. Under the terms of the Settlement Agreement, the total settlement before legal fees and costs was \$1,000,000; \$535,000 was paid in March 2012 (\$379,000 net received by the Company) and \$465,000 (\$331,000 net received by the Company) was paid in August 2012. We recorded the net amounts as a component of non-operating income during the year ended December 31, 2012.

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**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 ( Superior Court ) naming Vermillion and Bio-Rad Laboratories, Inc. ( Bio-Rad ) as defendants (the State Court lawsuit ). In connection with the State Court lawsuit, MAS alleged that we breached our license agreement with MAS by transferring certain SELDI technology to Bio-Rad without obtaining MAS 's consent. MAS listed the value of its claim as in excess of \$5,000,000. Thereafter, the Superior Court ordered that the dispute be arbitrated before the Judicial Arbitration and Mediation Service ( JAMS ). MAS filed its demand for arbitration in 2010 and the arbitration hearing occurred in 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 to MAS either through February 21, 2013 or until cumulative royalty payments reach \$10 million, whichever comes first, and ordered that such royalties should be based on total GAAP revenues less revenues attributable to certain excluded entities, not just SELDI-related revenues. Subsequently, the parties agreed to resolve (i) any and all remaining royalty obligations owed to MAS from us and (ii) any and all claims for fees and costs that we had against MAS in return for Vermillion making a one-time payment to MAS of \$35,000. We submitted to JAMS a mutual stipulation consistent with that agreement and the Arbitrator entered a final arbitration award incorporating that stipulation on May 21, 2012. At our request, the Superior Court (i) confirmed the final arbitration award and (ii) entered the final arbitration award as the final judgment in this case on July 26, 2012.

***Bio-Rad Laboratories, Inc. Matters***

On November 13, 2006, we completed the Instrument Business Sale to Bio-Rad. The Instrument Business Sale included the SELDI technology, ProteinChip arrays and accompanying software. Pursuant to the terms of the sales agreement, the total sales price was \$20,000,000, of which \$16,000,000 was paid by Bio-Rad to us at the closing of the transaction on November 13, 2006. A total of \$4,000,000 was held back from the sales proceeds contingent upon our meeting certain obligations, of which \$2,000,000 was subsequently paid to us and \$307,000 was paid to settle certain employee termination indemnifications in fiscal 2007. From the amounts held back and interest thereon, \$1,830,000 was being held in escrow as of December 31, 2011 to serve as security for us to fulfill certain obligations.

In August 2009, Bio-Rad also filed a proof of claim in the bankruptcy case for indemnification of the MAS lawsuit. Management has subsequently received a final arbitration ruling from JAMS and settled the MAS claim. At our request, the Superior Court (i) confirmed the final arbitration award and (ii) entered the final arbitration award as the final judgment in this case on July 26, 2012. Thus, we believe that the possibility of any material loss from the indemnification of the MAS lawsuit is remote.

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 from Bio-Rad. In October 2009, Bio-Rad filed a proof of claim in our bankruptcy case based on certain contract claims and alleged breach of the manufacture and supply agreement for approximately \$1,000,000.

In April 2012, we resolved the four contract claims made by Bio-Rad arising from the Instrument Business Sale. In exchange for a final settlement of these non-contingent claims, Bio-Rad received \$700,000 from the escrow account established by the Company for the sale transaction, the Company was returned approximately \$1,080,000 from the escrow account. The final \$50,000 was returned to the Company in September 2012 after final resolution of the MAS lawsuit. We reversed \$375,000 of general and administrative expense accrued in previous periods during the year ended December 31, 2012 representing the accrued estimated liability in excess of the \$700,000 settlement amount. We recognized the resulting gain on sale of instrument business of \$1,830,000 from the release of the escrow account during the year ended December 31, 2012.

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***Robert Goggin and György Bessenyei Litigation***

On May 25, 2012, György B. Bessenyei and Robert S. Goggin, III, both stockholders of Vermillion, filed a verified complaint in the Delaware Court of Chancery (the Court) against Vermillion, each current member of our Board of Directors, and Gail S. Page. On June 1, 2012, Mr. Bessenyei and Mr. Goggin filed an amended verified complaint that was substantially similar to the verified complaint. The amended verified complaint contains the following causes of action: breach of fiduciary duty under two standards, declaratory relief, preliminary injunctive relief, and permanent injunctive relief. The allegations in the amended verified complaint challenge the recent adoption by the Board of Directors of an amendment to our bylaws eliminating the board seat formerly held by Ms. Page. As previously disclosed by Vermillion, on May 15, 2012, Ms. Page was terminated without cause as Vermillion's President and Chief Executive Officer, and, upon her termination, Ms. Page resigned her seat on the Board of Directors. For a variety of reasons, including an effort to streamline Vermillion's organization and extend its cash runway, the Board of Directors amended our bylaws to eliminate the vacant board seat, thereby reducing the size of the Board of Directors from seven to six members. This effort to streamline Vermillion's organization had begun in January 2012, when the Board of Directors amended the bylaws to eliminate an additional (eighth) seat on the Board of Directors. Mr. Bessenyei and Mr. Goggin claim that the Board of Directors' decision to eliminate the seat on May 15, 2012 was a breach of its fiduciary duties, alleging that the Board of Directors' actions were intended to prevent Mr. Bessenyei's and Mr. Goggin's nominees from both being able to be elected to the Board of Directors, and to entrench the Board of Directors' current members. Among other things, Mr. Bessenyei and Mr. Goggin sought to have the Court declare null and void the May 15, 2012 amendment to the bylaws, and award to Mr. Bessenyei and Mr. Goggin the costs and fees incurred by them in the action.

The parties negotiated a scheduling order, which was approved on June 6, 2012, setting trial in this expedited action to start on July 31, 2012. On June 13, 2012, Vermillion and the other defendants filed an answer. The parties then engaged in extensive discovery, including document production, service of interrogatory responses, and the taking of depositions. On July 26, 2012, Vermillion and the other defendants filed a motion to dismiss the case arguing that plaintiffs and their counsel provided improperly notarized documents verifying the complaint, amended complaint and discovery responses. On November 16, 2012, the Court dismissed the lawsuit with prejudice. The plaintiffs filed a notice of appeal of that dismissal order on December 10, 2012, and filed their opening appellate brief on February 1, 2013. On February 12, 2013, the Delaware Supreme Court denied Vermillion and the other defendants' motion to summarily affirm. Vermillion and the other defendants are in the process of preparing an appellate answering brief which will be filed by March 4, 2013. No hearing date on the appeal has been set by the Delaware Supreme Court.

***György Bessenyei Annual Shareholder Meeting Litigation***

On January 9, 2013, György B. Bessenyei, a stockholder of Vermillion, filed a verified complaint in the Delaware Court of Chancery (the Court) against Vermillion, and each current member of our Board of Directors. The complaint contains a cause of action for violation of Section 211 of the General Corporation Law of Delaware. The allegations in the complaint relate to the 2012 annual shareholder meeting which had not yet been held due to a scheduling order entered in the Goggin and Bessenyei litigation discussed above. The complaint seeks to have the Court compel Vermillion to hold its annual shareholder meeting and to award to Mr. Bessenyei the costs and fees incurred by him in the action. On January 16, 2013, the parties held a scheduling conference with the Court. On January 18, 2013, Vermillion filed its preliminary proxy setting the annual meeting date for March 21, 2013. Thereafter, both parties submitted competing proposed orders related to the upcoming annual shareholder meeting. The Court has not yet signed either order.

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

**Table of Contents****NOTE 8: COMMON STOCK****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 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 \$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 expired unexercised in 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.

Our outstanding warrants from the August 2007 offering were classified as liabilities in accordance with ASC 815, which required 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.

We had no warrants required to be classified as a liability at December 31, 2012. At December 31, 2011, 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 was de minimis and for the year ended December 31, 2011, we recorded a gain of \$378,000 in the consolidated statement of operations under ASC 815.

**Warrants**

Warrants outstanding as of December 31, 2012 and 2011 were as follows:

Issuance Date	Expiration Date	Exercise Price per Share	Number of Shares Outstanding under Warrant	
			December 31, 2012	December 31, 2011
August 29, 2007	August 29, 2012	9.25*		195,012
November 1, 2011	October 31, 2013	3.23	21,000	21,000
May 1, 2012	April 30, 2014	3.18	21,000	
November 1, 2012	October 31, 2014	1.93	21,000	
			63,000	216,012

\* The exercise price of the warrants issued on August 29, 2007 was adjustable in accordance with the term of the warrants. We periodically issue common stock warrants to a vendor in exchange for services. The warrants vest pro-rata on a monthly basis over a six month period and expire two years after issuance. The value of the warrants as determined by the Black-Scholes model was not significant and is classified as equity.



**Table of Contents****Debtor s Incentive Plan**

In connection with our voluntary petition for relief (our Bankruptcy Filing ) under Chapter 11 of the United States Bankruptcy Code ( Chapter 11 ) in the United States Bankruptcy Court for the District of Delaware (the Bankruptcy Court ), 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 and former 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 in June 2009, the Court entered an Order approving the Incentive Plan Motion (the Incentive Plan Order ). The Debtor s Incentive Plan was 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. In April 2010, our counsel, the Official Committee of the Equity Security Holders, and the Directors submitted a proposed settlement to the Bankruptcy Court and 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 vested 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 in January 2010 when the Bankruptcy Courts issued a confirmation order approving our Reorganization Plan. There were no Debtor s Incentive Plan expenses for the year ended December 31, 2012. For the year ended December 31, 2011, we incurred \$1,657,000 recorded in general and administrative expenses and we distributed 75,637 shares of common stock to the Directors under the Debtor s Incentive Plan.

**NOTE 9: ACCUMULATED OTHER COMPREHENSIVE LOSS**

The components of accumulated other comprehensive loss as of December 31, 2012 and 2011, were as follows:

(In thousands)	Year Ended December 31,	
	2012	2011
Cumulative translation adjustment		(153)
Accumulated other comprehensive loss	\$	\$ (153)

**Table of Contents****NOTE 10: LOSS PER SHARE**

The reconciliation of the numerators and denominators of basic and diluted loss per share for the years ended December 31, 2012 and 2011 was as follows:

<b>(In thousands, except per share data)</b>	<b>Loss (Numerator)</b>	<b>Shares (Denominator)</b>	<b>Per Share Amount</b>
<b>Year ended December 31, 2011:</b>			
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)
<b>Year ended December 31, 2012:</b>			
Net loss basic	\$ (7,146)	15,010,868	\$ (0.48)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards			
Net loss diluted	\$ (7,146)	15,010,868	\$ (0.48)

Due to net losses for the years ended December 31, 2012 and 2011, diluted loss per share is calculated using the weighted average number of common shares outstanding and excludes the effects of potential common stock 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, 2012 and 2011 were as follows:

	<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
Stock options	1,092,374	930,060
Stock warrants	63,000	216,012
Restricted stock units	8,334	114,748
Potential common shares	1,163,708	1,260,820

**NOTE 11: EMPLOYEE BENEFIT PLANS****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 8,333 and 21,833 shares of common stock were exercised during the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, options to purchase 336,656 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.

**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, 2012 and 2011.

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 78,415 and 42,250 of these shares of common stock to our officers during the years ended December 31, 2012 and 2011, respectively.

In September 2011, our Board of Directors approved the Company making income tax gross-up payments to our now former 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 \$36,000 and \$22,000 related to this letter agreement during the year ended December 31, 2012 and 2011, respectively. All 85,000 common shares have been distributed as of December 31, 2012.

During the year ended December 31, 2012, we issued 212,500 shares of restricted stock from the 2010 Plan having a fair value of \$414,000 to the Board of Directors as payment for services rendered in 2012. 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.

The activity related to shares available for grant under the 2000 Plan and 2010 Plan for the years ended December 31, 2012 and 2011 were as follows:

	<b>2000 Stock Plan</b>	<b>2010 Stock Option Plan</b>	<b>Total</b>
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 available at December 31, 2011		628,675	628,675
Options canceled	251,058	136,595	387,653
Reduction in shares reserved	(251,058)		(251,058)
Options granted		(558,300)	(558,300)
Restricted stock units canceled		28,001	28,001
Restricted stock units granted		(212,500)	(212,500)
Shares available at December 31, 2012		22,471	22,471

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The stock option activity under the 2000 Plan and 2010 Plan for the years ended December 31, 2012 and 2011 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
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
Granted	558,300	1.54		
Exercised	(8,333)	0.75		
Canceled	(387,653)	21.57		
Options outstanding at December 31, 2012	1,092,374	\$ 4.17	\$ 20	6.23
<b>Shares exercisable:</b>				
December 31, 2012	606,215	\$ 5.73	\$ 8	3.85
<b>Shares expected to vest:</b>				
December 31, 2012	398,650	\$ 2.23	\$ 12	9.20

The range of exercise prices for options outstanding and exercisable at December 31, 2012 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 \$1.61	115,500	\$ 1.16	9.45	21,239	\$ 0.95
1.62 1.62	437,288	\$ 1.62	6.90	179,338	\$ 1.62
1.63 2.04	202,000	1.98	8.04	94,734	2.00
2.05 2.30	136,709	2.30	2.27	135,209	2.30
2.31 5.16	24,430	4.38	8.23	10,795	4.39
5.17 10.20	49,049	9.20	2.52	48,059	9.19
10.21 14.70	71,349	13.35	2.44	69,546	13.40
14.71 86.40	56,049	26.67	4.61	47,295	26.31
\$0.01 \$86.40	1,092,374	\$ 4.17	6.23	606,215	\$ 5.73

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2012	\$ 7	\$ 525
Year ended December 31, 2011	\$ 52	\$ 1,218

**Table of Contents****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, 2012 and 2011 were as follows:

	Year Ended December 31,	
	2012	2011
Dividend yield	%	%
Volatility	78%	77%
Risk-free interest rate	1.32%	1.28%
Expected lives (years)	6.0	5.7
Weighted average fair value	\$ 1.04	\$ 1.60

The allocation of stock-based compensation expense by functional area for the years ended December 31, 2012 and 2011 was as follows:

(in thousands)	Year Ended December 31,	
	2012	2011
Research and development	\$ 112	\$ 683
Sales and marketing	203	158
General and administrative	942	2,442
Total	\$ 1,257	\$ 3,283

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, 2012, total unrecognized compensation cost related to nonvested stock option awards was \$531,000 and the related weighted average period over which it is expected to be recognized was 1.77 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 .

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, 2012 and 2011 as follows:

(in thousands)	Year Ended December 31,	
	2012	2011
Research and development	\$ 15	\$ 3
Sales and marketing		
General and administrative	23	4
Total	\$ 38	\$ 7



**Table of Contents****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, 2012 and 2011, we have not contributed to the 401(k) Plan.

**NOTE 12: INCOME TAXES**

Domestic and foreign components of loss before income taxes for the years ended December 31, 2012 and 2011 were as follows:

(in thousands)	Year Ended December 31,	
	2012	2011
Domestic	\$ (7,052)	\$ (17,696)
Foreign	(94)	(94)
	\$ (7,146)	\$ (17,790)

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, 2012 and 2011. There was no income tax expense or benefit for the years ended December 31, 2012 or 2011.

The components of deferred tax assets (liabilities) at December 31, 2012 and 2011 were as follows:

(in thousands)	Year Ended December 31,	
	2012	2011
Deferred tax assets:		
Depreciation and amortization	\$ 8,955	\$ 11,158
Other	1,431	1,617
Net operating losses	46,918	42,443
Total deferred tax assets	57,304	55,218
Valuation allowance	(57,296)	(55,210)
Net deferred tax assets	\$ 8	\$ 8
Deferred tax liabilities:		
Other	\$ (8)	\$ (8)
Total deferred tax liabilities	\$ (8)	\$ (8)
Net deferred tax asset (liability)	\$	\$

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The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2012 and 2011 was as follows:

	<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
Tax at federal statutory rate	34 %	34 %
State tax, net of federal benefit	3	2
Valuation allowance	(31)	(17)
Change in warrant valuation		1
Net operating loss and credit reduction due to section 382 limitations	(35)	(11)
Permanent items	25	(9)
Other	4	
Effective income tax rate	%	%

As of December 31, 2012, we had a net operating loss of approximately \$133,000,000 for federal and \$108,000,000 for state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2017 for federal purposes. The state carryforwards began to expire in 2012. In 2012, approximately \$2,100,000 of state net operating loss expired and approximately \$1,800,000 will expire in 2013. 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.

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, we had \$6,300,000 of net operating loss carryforwards from our Japan operations. We liquidated our Japanese subsidiary in December 2012. Accordingly, the deferred tax asset and related valuation allowance were written off.

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 \$57,296,000 and \$55,210,000 at December 31, 2012 and 2011, respectively. The increase of \$2,086,000 between 2012 and 2011 is primarily due to adjustments to the domestic deferred tax assets relating to net operating losses.

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, 2012, our federal returns for the years ended 2009 through the current period and most state returns for the years ended 2008 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 2009 and 2008, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2011 reflect research and development carryforwards of \$5,586,000 and \$5,191,000,

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respectively. We have recognized additional deferred tax assets for federal and California research and development credits of \$69,000 and \$51,000 for the year ended December 31, 2012, respectively. As of December 31, 2012, our gross unrecognized tax benefits are approximately \$10,897,000 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, 2010	\$ 5,450	\$ 5,089	\$ 10,539
Increase in tax position during 2011	136	102	238
Balance at December 31, 2011	\$ 5,586	\$ 5,191	\$ 10,777
Increase in tax position during 2012	69	51	120
Balance at December 31, 2012	\$ 5,655	\$ 5,242	\$ 10,897

The increase for the year ended December 31, 2012 relates to a tax position taken during the current year. The increase for the year ended December 31, 2011 is related to tax positions taken during 2011 and prior years. If the \$10.9 million of unrecognized income tax benefit is recognized, approximately \$10.9 million 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 relate to the unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations and comprehensive loss. We have not recorded any interest or penalties as a result of uncertain tax positions as of December 31, 2012 and 2011. Accrued interest and penalties would be included within the related liability in the consolidated balance sheet.

**NOTE 13: OTHER RELATED PARTY TRANSACTIONS****Consulting Agreements**

On June 17, 2011, we entered into a consulting agreement with Bruce A. Huebner, a member of our Board of Directors. Pursuant to the terms of the consulting agreement, Mr. Huebner provided consulting services regarding sales, marketing, business development and corporate strategy and was paid \$200 per hour. For the year ended December 31, 2012 and 2011, the total amount of consulting fee expense for Mr. Huebner was \$5,000 and \$9,000, respectively. On November 27, 2012, we announced the appointment of Mr. Huebner as Interim Chief Executive Officer. Mr. Huebner continues to serve on our Board of Directors.

On December 3, 2012, we entered into a consulting agreement with our former President and Chief Executive Officer and director, Gail S. Page. Pursuant to the terms of the consulting agreement, Ms. Page will assist the Company as needed, including providing advice and recommendations with respect to the development and commercialization of the Company's existing and future diagnostic tests, and managing and developing relationships with existing and future collaborators and partners. She will provide a minimum of 48 and a maximum of 96 hours of consulting services per month. In consideration for such services, we will pay Ms. Page a monthly fee of \$18,000, plus \$250 for each hour of services provided in excess of the 48 hour minimum. The Consulting Agreement has an initial term of six months, after which it may be renewed for an additional six month term by mutual agreement of the Company and Ms. Page. For the year ended December 31, 2012, the total amount of consulting fee expense to Ms. Page was \$18,000. The consulting agreement has been terminated with an effective date of March 15, 2013.

In November 2011, we entered into a consulting agreement with our former Senior Vice President and Chief Science Officer, Eric T. Fung, M.D., Ph.D. Pursuant to the terms of the consulting agreement, Dr. Fung served as our Chief Medical Officer and a member of our Scientific Advisory Board. Dr. Fung's consulting agreement and Scientific Advisory Board services were terminated in June 2012. For the year ended December 31, 2012 and 2011, the total amount of consulting fee expense for Dr. Fung was \$27,000 and \$6,000, respectively. During 2012, Dr. Fung also continued to vest in restricted stock with a fair value of \$11,000 until the termination of the consulting agreement.



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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 provided consulting services. This consulting agreement was terminated in June 2012. For the year ended December 31, 2012, the total amount of consulting fee expense to our former Vice President of Strategy was \$23,000 and the fair value of continued vesting in restricted stock was \$1,000 until the termination of the consulting agreement.

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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 1, 2013

/s/ Bruce A. Huebner  
 Bruce A. Huebner  
 Interim Chief Executive Officer  
  
 (Principal Executive Officer)

Date: March 1, 2013

/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.

<b>Name</b>	<b>Title</b>	<b>Date</b>
/s/ Bruce A. Huebner Bruce A. Huebner	Interim Chief Executive Officer (Principal Executive Officer)	March 1, 2013
/s/ Eric J. Schoen Eric J. Schoen	Chief Accounting Officer (Principal Financial Officer)	March 1, 2013
/s/ James S. Burns James S. Burns	Chairman of the Board of Directors	March 1, 2013
/s/ John F. Hamilton John F. Hamilton	Director	March 1, 2013
/s/ Peter S. Roddy Peter S. Roddy	Director	March 1, 2013
/s/ Carl Severinghaus Carl Severinghaus	Director	March 1, 2013
/s/ William C. Wallen, Ph.D. William C. Wallen, Ph.D.	Director	March 1, 2013

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Exhibit Number	Exhibit Description	Form	Incorporated by Reference			Filed
			File No.	Exhibit	Filing Date	Herewith
2.1	Findings of Fact, Conclusions of Law and Order Confirming Debtor s (Vermillion Inc. s) Second Amended Plan of Reorganization Under Chapter 11 of the Bankruptcy Code dated January 7, 2010	8-K	000-31617	2.1	January 12, 2010	
3.1	Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated January 22, 2010	8-K	000-31617	3.1	January 25, 2010	
3.2	Third Amended and Restated Bylaws of Vermillion, Inc., as amended effective May 15, 2012					ii
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	
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	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed
		Form	File No.	Exhibit	Filing Date	Herewith
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	
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	

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Exhibit Number	Exhibit Description	Form	Incorporated by Reference			Filed
			File No.	Exhibit	Filing Date	Herewith
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	
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	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed
		Form	File No.	Exhibit	Filing Date	Herewith
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	
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	

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Exhibit Number	Exhibit Description	Form	Incorporated by Reference			Filed
			File No.	Exhibit	Filing Date	Herewith
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	
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 Correllogic Systems, Inc., dated November 8, 2011	10-K	001-34810	10.50	March 27, 2012	
10.51	Employment Agreement between Eric J. Schoen and Vermillion, Inc. dated April 4, 2012 #	8-K	001-34810	10.1	April 10, 2012	
10.52	Employment Agreement between William Creech and Vermillion, Inc. dated April 4, 2012 #	8-K	001-34810	10.2	April 10, 2012	
10.53	Settlement Agreement and Release between Vermillion, Inc. and Oppenheimer & Co., Inc. dated February 9, 2012	10-K/A	001-34810	10.51	May 30, 2012	
10.54	Employment Agreement between Bruce A. Huebner and Vermillion, Inc. dated November 26, 2012 #	8-K	001-34810	10.1	November 28, 2012	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed
		Form	File No.	Exhibit	Filing Date	Herewith
10.55	Consulting Agreement between Gail S. Page and Vermillion, Inc. dated December 3, 2012 #	8-K	001-34810	10.2	November 28, 2012	
10.56	Separation Agreement and Release between Gail Page and Vermillion, Inc. dated December 7, 2012 #	8-K	001-34810	10.1	December 11, 2012	
14.1	Code of Ethics	8-K	001-34810	14.1	December 7, 2010	
21.0	Subsidiaries of Registrant					ü
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm					ü
23.2	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)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					(1)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					(1)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					(1)

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



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(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.