VERMILLION, INC. Form 10-K March 31, 2008

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
 OF THE SECURITIES EXCHANGE ACT OF 1934.
 For the fiscal year ended December 31, 2007.

or

o TRANSITION REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from to .

Commission File Number: 000-31617

#### Vermillion, Inc.

(Exact name of registrant as specified in its charter)

**Delaware** 

(State or other jurisdiction of incorporation or organization)

6611 Dumbarton Circle, Fremont, California

(Address of principal executive offices)

33-0595156

(I.R.S. Employer Identification No.)
94555

7in Code

(Zip Code)

Registrant s telephone number, including area code:
(510) 505-2100

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, Par Value \$0.001 Per Share

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

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 o No b

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 o No b

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 the 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. b

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 o Accelerated filer o Non-accelerated filer o Smaller reporting company b

(Do not check if a smaller reporting company)

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

The aggregate market value of voting common stock held by non-affiliates of the Registrant is \$23,249,513 and is based upon the last sales price as quoted on the NASDAQ Capital Market as of June 30, 2007.

As of February 29, 2008, the Registrant had 6,380,197 shares of common stock, par value \$0.001 per share, outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE:**

Proxy Statement for the June 11, 2008, Annual Meeting of Stockholders is incorporated by reference into Part III.

# Vermillion, Inc. and Subsidiaries

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*Vermillion* is a trademark of Vermillion, Inc. *ProteinChip is* registered trademark of Bio-Rad Laboratories, Inc. *BioSepra* is a registered trademark of Pall Corporation.

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#### PART I

#### **Forward Looking Statements**

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

projections of the Company s future revenue, results of operations and financial condition;

anticipated deployment, capabilities and uses of Vermillion s products and Vermillion s product development activities and product innovations;

the importance of proteomics as a major focus of biology research;

competition and consolidation in the markets in which the Company competes;

existing and future collaborations and partnerships;

the utility of biomarker discoveries;

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

our plans to develop and commercialize diagnostic tests through Vermillion s strategic alliance with Quest Diagnostics Incorporated (Quest);

our ability to comply with applicable government regulations;

our ability to expand and protect Vermillion s intellectual property portfolio;

our ability to decrease general and administrative costs;

our ability to decrease sales and marketing costs;

our ability to decrease research and development costs;

anticipated future losses;

expected levels of capital expenditures;

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

the period of time for which the Company s existing financial resources, debt facilities and interest income will be sufficient to enable the Company to maintain current and planned operations; and

the market risk of the Company s investments.

These 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 new diagnostic products; managing the Company's operating expenses and cash resources that is consistent with our plans; our ability to conduct new diagnostic product development using both Vermillion's internal research and development resources, and collaboration partners within the budgets and time frames we have established; the ability of the ProteinChip technology to discover protein biomarkers that have diagnostic, theranostic and/or drug development utility; the continued emergence of proteomics as a major focus of biological research and drug

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discovery; and our ability to protect and promote Vermillion s proprietary technologies. We believe it is important to communicate our expectations to Vermillion s investors. However, there may be events in the future that we are not able to accurately predict or that we do not fully control that could cause actual results to differ materially from those expressed or implied in the Company s forward-looking statements.

#### Item 1. Business

## **Company Background**

Vermillion, Inc. ( Vermillion ; Vermillion and its wholly owned subsidiaries are collectively referred to as the Company ) is dedicated to the discovery, development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Vermillion uses the process of utilizing advanced protein separation methods to identify and resolve variants of specific biomarkers (known as translational proteomics ) for developing a procedure to measure a property or concentration of an analyte (known as an assay ) and commercializing novel diagnostic tests.

Management ( we , us or our ) plans to concentrate its development of novel diagnostic tests in the fields of oncology, hematology, cardiology and women s health with the initial focus on ovarian cancer. Vermillion will also 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 in addition to the three-year strategic alliance agreement with Quest. Current and former academic and research institutions that Vermillion has 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; The Ohio State University Research Foundation ( OSU ); and Stanford University ( Stanford ).

Prior to the November 13, 2006, sale of the Company's assets and liabilities of its protein research products and collaborative services business (the Instrument Business Sale) to Bio-Rad Laboratories, Inc. (Bio-Rad), the Company developed, manufactured and sold ProteinChip Systems for life sciences research. This patented technology is recognized as Surface Enhanced Laser Desorption/Ionization (SELDI). The systems consist of ProteinChip Readers, ProteinChip Software and related accessories, which were used in conjunction with consumable ProteinChip Arrays. These products were sold primarily to pharmaceutical companies, biotechnology companies, academic research laboratories and government research laboratories. The Company also provided research services through its Biomarker Discovery Center laboratories, and offered consulting services, customer support services and training classes to its customers and collaborators.

### **Financing and Organization**

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 of Ciphergen Biosystems, Inc., Vermillion had its initial public offering on September 28, 2000, and began trading on the NASDAQ National Market under the ticker symbol CIPH. Vermillion had a 1 for 10 reverse stock split of Vermillion s common stock effective at the close of business on March 3, 2008. Accordingly, all share and per share amounts were adjusted to reflect the impact of the 1 for 10 reverse stock split in this Annual Report on Form 10-K.

On August 22, 2003, Vermillion closed the sale of \$30,000,000 in aggregate principal of the 4.50% convertible senior notes due September 1, 2008. On November 15, 2006, certain holders of the 4.50% convertible senior notes agreed to

exchange and redeem \$27,500,000 in aggregate principal for \$16,500,000 in aggregate principal of the 7.00% convertible senior notes due September 1, 2011, and \$11,000,000 in cash in addition to the accrued and unpaid interest on the 4.50% convertible senior notes of \$254,000. The remaining \$2,500,000 in aggregate principal of the 4.50% convertible senior notes and the \$16,500,000 in aggregate principal of the 7.00% convertible senior notes are convertible into 27,208 and 825,000 shares of Vermillion common stock, respectively.

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On July 22, 2005, Vermillion entered into a three-year strategic alliance agreement with Quest Diagnostic Incorporated (Quest) to develop and commercialize up to three diagnostic tests. In connection with this strategic alliance, Vermillion sold 622,500 shares of Vermillion common stock and a warrant to purchase 220,000 shares of Vermillion common stock at \$35.00 per share to Quest for \$14,954,000 in net proceeds. In addition, Quest agreed to provide Vermillion with \$10,000,000 secured line of credit to pay certain costs and expenses related to this strategic alliance. This secured line of credit is forgivable based upon the achievement of certain milestones related to the development, regulatory approval and commercialization of certain diagnostic tests. If Vermillion fails to achieve these milestones, the outstanding balance of this secured line of credit will become due and payable on July 22, 2010.

On November 13, 2006, the Company completed the Instrument Business Sale to Bio-Rad, which allowed the Company to concentrate its resources on developing clinical protein biomarker diagnostic products and services. The net proceeds from the Instrument Business Sale and sale of 308,642 shares of Vermillion common stock to Bio-Rad amounted to \$18,218,000. In connection with the Instrument Business Sale, \$2,000,000 is being held in escrow until November 13, 2009, to serve as security for Vermillion to fulfill certain obligations, and \$2,000,000 was withheld by Bio-Rad from the sales proceeds until the issuance of a reexamination certificate confirming United States Patent No. 6,734,022 (the 022 Patent ). On October 23, 2007, the United States Patent and Trademark Office issued a reexamination certificate of the 022 Patent, and on November 9, 2007, the Company received \$2,000,000 from Bio-Rad that was withheld from the proceeds of the Instrument Business Sale.

On June 29, 2007, the stockholders approved amendments to the Certificate of Incorporation to increase the number of authorized shares of common stock from 80,000,000 to 150,000,000 and to change the name of the company from Ciphergen Biosystems, Inc. to Vermillion, Inc. On July 13, 2007, Vermillion amended and restated its Certificate of Incorporation with the State of Delaware for the increased authorized shares and on August 21, 2007, Vermillion amended its Certificate of Incorporation to reflect the name change, which reflects the transition of the Company from its historic roots as a proteomics research products business to a novel diagnostic testing business. In conjunction with the name change, Vermillion changed its common stock ticker symbol on the NASDAQ Capital Market from CIPH to VRML.

On August 29, 2007, Vermillion completed a private placement sale of 2,451,309 shares of its common stock and warrants to purchase up to an additional 1,961,047 shares of its common stock with an exercise price of \$9.25 per share and an expiration date of August 29, 2012, to a group of new and existing investors for \$20,591,000 in gross proceeds. In this private placement sale, Quest acquired 238,095 shares of Vermillion common stock and warrants to purchase 190,476 shares of Vermillion common stock at \$9.25 per share for \$2,000,000.

On August 15, 2007, Vermillion was notified by NASDAQ Listing Qualifications that it did not comply with Marketplace Rule 4310(c)(3) for continued inclusion, and as required by Marketplace Rule 4310(c)(8)(C), Vermillion had 30 days, or until September 14, 2007, to regain compliance. Marketplace Rule 4310(c)(3) requires Vermillion to (A) have minimum stockholders equity of \$2,500,000, (B) have a minimum common stock market value of \$35,000,000 or (C) have net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years. On September 14, 2007, NASDAQ Listing Qualifications notified Vermillion that it had regained compliance with Marketplace Rule 4310(c)(3) as a result of the market value of Vermillion common stock exceeding \$35,000,000 for 10 consecutive business days. Subsequently, on February 22, 2008, Vermillion was notified by NASDAQ Listing Qualifications that it did not comply with Marketplace Rule 4310(c)(3) for continued inclusion as a result of the market value of Vermillion common stock falling below \$35,000,000 for 10 consecutive business days, and as required by Marketplace Rule 4310(c)(8)(C), Vermillion had 30 days, or until March 24, 2008, to regain compliance. Vermillion did not regain compliance by March 24, 2008, and, accordingly, on March 25, 2008, Vermillion received written notification from NASDAQ Listing Qualifications (the Staff Determination Notice) that Vermillion s securities would be subject to delisting as a result of the deficiency unless Vermillion requests a hearing before a NASDAQ Listing Qualifications Panel. The

Company plans to timely request a hearing before the NASDAQ Listing Qualifications Panel to address the market value of listed securities deficiency, which will stay any action with respect to the Staff Determination Notice until the NASDAQ Listing Qualifications Panel renders a decision subsequent to the hearing. Vermillion anticipates that the hearing will be scheduled to occur within the next 45 days. There can be no assurance that the Panel will grant Vermillion s request for continued listing.

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Additionally, on September 6, 2007, Vermillion was notified by NASDAQ Listing Qualifications that Vermillion s common stock bid price closed below the minimum \$1.00 per share requirement for continued inclusion by Marketplace Rule 4310(c)(4), and as required by Marketplace Rule 4310(c)(8)(D), Vermillion had 180 days, or until March 4, 2008, to regain compliance. To regain compliance, the bid price of Vermillion s common stock must close at \$1.00 per share or more for a minimum of 10 consecutive business days. In an effort to meet the minimum \$1.00 per share requirement for continued inclusion by Marketplace Rule 4310(c)(4), Vermillion held a Special Meeting of Stockholders on February 14, 2008. At the Special Meeting of Stockholders, the stockholders of Vermillion approved the proposal to authorize the Board of Directors in its discretion, without further authorization of Vermillion s stockholders, to amend Vermillion s Certificate of Incorporation to effect a reverse split of Vermillion s common stock by a ratio of between 1 for 6 to 1 for 10. To regain compliance with Marketplace Rule 4310(c)(4), the Board of Directors approved on February 15, 2008, a 1 for 10 reverse stock split (the Reverse Stock Split ) of Vermillion s common stock effective at the close of business on Monday, March 3, 2008. Cash will be paid for post-split fractional shares based on the average closing sales price for the 20 trading days immediately before the effective time. On March 4, 2008, Vermillion s common stock began trading under the Reverse Stock Split basis. Additionally, beginning on March 4, 2008, Vermillion s common stock will trade for a period of 20 trading days under ticker symbol VRMLD as an interim symbol to denote its new status. After this 20 trading day period, Vermillion s common stock will resume trading under the ticker symbol VRML . Subsequently, on March 18, 2008, NASDAQ Listing Qualifications notified Vermillion it had regained compliance with Marketplace Rule 4310(c)(4) with Vermillion s common stock closing above \$1.00 per share or greater for at least 10 consecutive business days.

In an effort to further streamline operations, the Company reduced its workforce by 9 employees during March 2008. As a result of the reduction in workforce, the Company had 19 employees as of March 31, 2008.

#### **Subsidiaries**

Vermillion has eight wholly owned subsidiaries of which one subsidiary, Ciphergen Biosystems International, Inc. (CBII), has three wholly owned subsidiaries. Eight of the eleven wholly owned subsidiaries are incorporated in Europe and Asia. The eight foreign wholly owned subsidiaries and CBII were established for the purpose of providing sales, marketing and technical support to the Instrument Business. As part of our future sales and marketing strategy, the Company is in the process of legally dissolving seven of the foreign wholly owned subsidiaries and only the subsidiary in Japan will remain. The other two subsidiaries are inactive.

### **Segment and Geographical Information**

The Company currently operates one reportable segment, novel diagnostic tests. Prior to the Instrument Business Sale to Bio-Rad, the Company operated one reportable segment, which was the protein research products and collaborative services business. See Note 19, Geographical Information, to the consolidated financial statements in Part II, Item 8, Financial Statements and Supplementary Data, for the Company is geographical information.

#### The Diagnostics Market

The economics of healthcare demand improved allocation of resources. Improved allocation of resources 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 February 2007 Jain PharmaBiotech report, the worldwide market for in vitro diagnostics ( IVDs ) in 2006 was approximately \$49.2 billion.

Vermillion has chosen to concentrate primarily in the areas of oncology, hematology, cardiology and women s health. Demographic trends suggest that, as the population ages, the burden from these diseases will increase and the demand for quality diagnostic, prognostic and predictive tests will increase. In addition, these areas generally lack quality

diagnostic tests and, therefore, we believe patient outcomes can be significantly improved by the development of novel diagnostic tests.

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

Consequently, measuring a single protein biomarker when multiple protein biomarkers may be altered in a complex disease is unlikely to provide meaningful information about the disease state. We believe that our approach of monitoring and combining multiple protein biomarkers using a variety of analytical techniques including mass spectrometry, will allow Vermillion 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.

## Competition

The diagnostics industry in which the Company operates 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 Vermillion or its collaborators;

develop diagnostic products that are more effective or cost-effective than those developed by Vermillion or its collaborators;

obtain regulatory clearance or approval of their diagnostic products more rapidly than Vermillion or its collaborators; or

obtain patent protection or other intellectual property rights that would limit the ability to develop and commercialize, or a customers ability to use Vermillion s or its collaborators diagnostic products.

The Company competes 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 the Company or its 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 the Company or its collaborators. For example, a clinical laboratory can either use reagents purchased from manufacturers other than the Company 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 the Company 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 the Company or its 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.

#### 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. The initial structure of a protein is determined by a single gene. The final 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

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about diseases, it does not provide a full understanding of disease processes. Vermillion is focused on converting recent advances in proteomics into clinically useful diagnostic tests.

#### Relationship between proteins and diseases

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

## Limitations of existing diagnostic approaches

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

#### Vermillion s solution

Vermillion s studies, particularly in ovarian cancer, have given Vermillion a better understanding of both the disease pathophysiology and the host response. By using multiple biomarkers, Vermillion is able to better encompass the disease and host response heterogeneity. In addition, by examining specific biomarkers with greater resolution, for example, post-translational modifications, we believe Vermillion can improve the specificity of its diagnostic biomarkers because these modifications reflect both the pathophysiology and host response. This is accomplished using an advanced protein separation system (integrated equipment, reagents and software) to identify combinations of specific biomarkers leading to commercialization of disease-specific assays.

Vermillion is applying translational proteomics research, development tools, and methods to analyze biological information in an attempt to discover associations between proteins, protein variants, protein-protein interaction and diseases. Vermillion intends to develop new diagnostic tests based on known and newly identified protein markers to help physicians predict an individual s predisposition for a disease in order to better characterize, monitor progression

of and select appropriate therapies for such disease. Our goals are to:

Develop novel diagnostic tests that address unmet medical needs, particularly in stratifying patients according to the risk of developing a disease, having a disease or failing a specific therapy for a disease;

Facilitate more efficient clinical trials of new therapeutics by providing biomarkers that stratify patients according to likelihood of response; and

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Identify biomarkers that can form the basis of molecular imaging targets.

The following table is a summary of certain diagnostic issues and Vermillion s solution:

Issue	Solution
Heterogeneity of disease	Emphasis on multi-biomarker panels
Poorly validated biomarkers	Expertise in study design incorporating internal and external validation  Large multi-site studies
Protein post-translational modifications that reduce specificity of assays	Mass spectrometry based assays to quantitate disease-specific forms

#### Addressing the heterogeneity of disease

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

## Validation of biomarkers through proper study design

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

When designing clinical studies, Vermillion begins 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, Vermillion designs its studies to include the appropriate cases and control groups. Vermillion further incorporates an initial validation component even within the discovery component. Vermillion places 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. To date, Vermillion has analyzed more than 2,500 samples from five additional medical centers. Additionally to date, Vermillion has examined over 300 samples in its breast cancer program, over 400 samples in its prostate cancer program and over 600 samples in its PAD program. In analyzing the complex proteomics data, Vermillion takes 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.

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#### Exploiting the power of mass spectrometry to improve assay specificity

The functional activity of proteins is often modulated by changes in its structure. Conventional approaches to assay proteins vary in their ability to detect these changes, and may depend on the specificity of the antibody to the original or altered forms of the proteins. Additionally, a conventional assay may inadvertently measure only one form of a protein while many other forms of this protein exist. Vermillion is use of mass spectrometry has advantages over traditional assay approaches due to its ability to distinguish two or more highly related protein species based on molecular mass, or in combination with chromatographic separation tools, such as with ProteinChip arrays, based on biochemical properties. Because most traditional assay approaches rely strictly on using antibodies to capture the intended biomarker, protein forms with a common epitope are not readily distinguished. For example, Vermillion is specifically addressing thrombotic thrombocytopenic purpura ( TTP ), a hematologic disease that affects mostly women and is a result of a deficiency in the A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 ( ADAMTS13 ) enzyme. Current assays rely on unwieldy western blots or alternately immunoblot, which are both low throughput and poorly quantitative. Vermillion is assay measures the product of the enzymatic reaction for ADAMTS13 enzyme directly, provides the quantitation necessary to distinguish TTP from other thrombocytopenic diseases, evaluates patient responses to therapy, and monitors patients during clinical remission to prevent recurrences of the disease.

#### Creating and maintaining a multi-disease product pipeline

Vermillion plans to develop potential diagnostic tests based on biomarkers discovered in its sponsored programs with academic collaborators, and through this in-license of biomarkers and assays from an installed base of hundreds of academic SELDI customers. The Company s past strategy of selling its SELDI systems to researchers in academic institutions, pharmaceutical companies and biotechnology companies has provided Vermillion with access to biomarkers that may potentially lead to additional diagnostic tests. Going forward, Vermillion and Bio-Rad have agreed to continue to identify SELDI users who may provide additional biomarker discoveries for Vermillion s diagnostics test pipeline. Additionally, Vermillion has the opportunity to identify biomarkers discovered on other proteomic platforms that will complement its existing product pipeline.

Vermillion has entered into collaboration, research and material transfer agreements with over 16 academic institutions and companies to support its large-scale clinical studies, which include ongoing clinical studies as well as future clinical studies. Some of Vermillion s major collaborations in the areas of oncology, hematology, cardiology and women s health are described below:

The Johns Hopkins University School of Medicine: Led by Dr. Daniel W. Chan, Director of the Clinical Chemical Division, this collaboration focuses on oncology (in particular, breast, prostate and ovarian cancer). Under this collaboration agreement with JHU, Vermillion provides research funding, ProteinChip Systems and ProteinChip Arrays. JHU provides laboratory space and equipment, clinical samples and scientists to perform the research. JHU has granted Vermillion an option to take a royalty-bearing exclusive worldwide license to commercialize any inventions resulting from the research. Vermillion s royalty obligations include minimum annual royalties, as well as running royalties on sales of products and services. On January 30, 2008, Vermillion renewed its research collaboration agreement with JHU. The agreement has an effective period from January 1, 2008, through December 31, 2010, with automatic one-year extensions for up to three additional years unless terminated by Vermillion or JHU.

The University of Texas M.D. Anderson Cancer Center: Led by Dr. Robert C. Bast, Jr., who discovered the tumor biomarker or biomarker cancer antigen 125 ( CA125 ), this collaboration focuses on ovarian cancer. CA125 found in women is most often associated with cancers of the reproductive tract, including the uterus, fallopian tubes and ovaries. Under Vermillion s research and license agreement with M.D. Anderson, Vermillion provides research

funding, ProteinChip Arrays and other consumables. M.D. Anderson provides clinical samples for research purposes. Both Vermillion and M.D. Anderson perform designated portions of the research. M.D. Anderson has granted Vermillion an option to negotiate and acquire a royalty-bearing, exclusive worldwide license to commercialize any inventions resulting from the research. Vermillion is currently in the process of negotiating license terms with M.D. Anderson with respect to certain patent applications covering biomarkers discovered under the collaboration.

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Stanford University: Led by Dr. John Cooke, this collaboration is directed at discovery, validation and characterization of novel biomarkers related to cardiovascular diseases, most notably peripheral arterial disease (PAD). Both Vermillion and Stanford perform designated portions of the research. On February 29, 2008, Vermillion entered into an exclusive agreement with Stanford to license the PAD assay.

The Katholieke Universiteit Leuven, Belgium: Led by Dr. Ignace Vergote, this collaboration is directed at discovery, validation, and characterization of novel biomarkers related to gynecological diseases. Under the terms of the research and license agreement, Vermillion will have exclusive rights to license discoveries made during the course of this collaboration. Vermillion will provide funding for sample collection from patients undergoing evaluation of a persistent mass and who will undergo surgical intervention. Each party will fund designated portions of the research.

The Ohio State University Research Foundation: Led by Dr. Haifeng Wu, this collaboration is directed at discovery, validation and characterization of novel biomarkers related to TTP and production of associated technology. TTP is a blood disorder characterized by low platelets, low red blood cell count (caused by premature breakdown of the cells), abnormalities in kidney function and nervous system abnormalities. It is usually caused by a decrease in the function of the ADAMTS13 enzyme. Vermillion will fund a portion of the costs incurred by OSU. Additionally, Vermillion has exclusive commercial licensing rights to the TTP assay and the option to exercise the rights for an exclusive commercial license of the discoveries made during the course of this collaboration. On November 6, 2007, Vermillion granted to OSU a limited, non-exclusive, non-transferable sublicense to purchase reagents from Vermillion for performing laboratory-developed test only.

The University of Texas Medical Branch: Led by Dr. John Petersen, this collaboration is focused on the discovery and development of new products for personalized, or targeted, medicine, particularly in the field of liver disease. Under Vermillion s research and license agreement with UTMB, UTMB provides clinical samples for research purposes. Both Vermillion and UTMB perform designated portions of the research. UTMB has granted Vermillion an option to negotiate and acquire a royalty-bearing, exclusive worldwide license to commercialize any inventions resulting from the research subject to the terms of a license agreement to be negotiated by the parties.

Together with its collaborators, Vermillion is currently conducting large-scale protein biomarker studies in the following areas: oncology, hematology, cardiology and women s health. Most of these studies involve the analysis of large numbers of samples from healthy and diseased individuals, or comparing patients with the disease of interest to those with related diseases for which clinical distinction is necessary. The goal of most of these studies is to identify sets of proteins that serve as biomarkers for a specific disease.

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The following table is a summary of disease field and the related status of Vermillion product development stage:

2005

	Estimated Treatment Decisions in the		
Disease Field	<b>United States</b>	<b>Specific Clinical Question</b>	<b>Product Development Stage</b>
Ovarian cancer	5,000,000	Screening and risk stratification of women with a suspicious pelvic mass	Final clinical evaluation(1)
	65,000	Prediction of recurrence/response to chemotherapy	Initial clinical evaluation(2)
	10,000,000	Surveillance of high-risk women	Initial discovery(3)
Breast cancer	54,000,000(4)	Triage to imaging modality	Initial clinical evaluation
	100,000	Enhanced response to chemotherapy	Initial discovery
Prostate cancer	30,000,000(5)	Screening and detection in conjunction with prostate specific antigen	Initial clinical evaluation
	230,000	Risk of recurrence	Initial clinical evaluation
Peripheral arterial disease	>12,000,000	Determination of risk of peripheral arterial disease	Final clinical evaluation
		Determination of risk of major adverse cardiovascular events in peripheral arterial disease	Initial discovery
Thrombotic thrombocytopenic Purpura	100,000	Diagnosis	Commercially available(6)

- (1) *Final clinical evaluation* means that a specific biomarker set has undergone a multi-site evaluation and assay development, and is undergoing final clinical evaluation tests prior to product launch.
- (2) *Initial clinical evaluation* means that a specific biomarker set is being evaluated in independent sample sets, generally from multiple medical centers. In some instances, candidate biomarkers have been discovered and are undergoing clinical evaluation experiments while additional biomarkers are being sought to improve the clinical performance.
- (3) *Initial discovery* means that studies, generally retrospective case control, are being conducted to discover and identify biomarkers. These studies are usually relatively small (<200) and examine samples from 1-2 medical centers, and a specific set of biomarkers for commercialization has not yet been determined.
- (4) Number of women aged 40-70, according to United States Census Bureau estimates.

- (5) Number of men aged 50-75, according to United States Census Bureau estimates.
- (6) Commercially available means the test is being offered through one or more venues.

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Further details regarding important developments in several of Vermillion s large-scale studies are set forth below.

Ovarian cancer. Commonly known as the silent killer, ovarian cancer leads to approximately 15,000 deaths each year in the United States. Approximately 20,000 new ovarian cancer cases are diagnosed each year, with the majority of the patients in the late stages of the disease in which the cancer has spread beyond the ovary. Unfortunately, ovarian cancer patients in the late stages of the disease have a poor prognosis, which leads to the high mortality rates. According to the American Cancer Society, when ovarian cancer is diagnosed at its earliest stages, 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 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. Ovarian cancer patients who are treated by the gynecologic oncologist have better outcomes than those patients treated by the general surgeon. Accordingly, an unmet clinical need is a diagnostic test that can provide adequate predictive value to stratify patients with a pelvic mass into high risk of invasive ovarian cancer versus those with a low risk of ovarian cancer, as well as a screening test for the diagnosis of early-stage ovarian cancer, which is essential for improving overall survival in patients.

Currently, no blood test exists to predict and stratify patients with a pelvic mass into high risk of invasive ovarian cancer versus those with a low risk of ovarian cancer, although a CA125 blood test is commonly used. The CA125 blood test, which is cleared by the FDA only for monitoring for recurrence of ovarian cancer, is absent in up to 50% of early stage ovarian cancer cases. Moreover, CA125 can be elevated in diseases other than ovarian cancer, including benign ovarian tumors 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 tumors. 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.

In August 2004, Vermillion, along with collaborators at JHU, UCL and M.D. Anderson, reported in a cancer research paper the discovery of three biomarkers that, when combined, provided higher diagnostic accuracy for early stage ovarian cancer than other biomarkers, such as CA125. The three biomarkers that Vermillion reported in the August 2004 cancer research paper form 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. The most recent data presented at the March 2007 Annual Meeting of the Society of Gynecologic Oncology described results from a cohort study. Vermillion was 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.

Vermillion has multiple ovarian cancer diagnostic tests in development. The most established of Vermillion s programs is the ovarian tumor triage test, which utilizes a panel of biomarkers to help identify women with ovarian cancer so they can be referred directly to a gynecologic oncologist for their initial surgery, thus improving survival rates and potentially reducing the number of second surgeries performed. Vermillion intends to submit in the coming

months the clinical trial data on the ovarian tumor triage test to the United States Food and Drug Administration (the FDA ) for clearance as an IVD test. Quest has accepted the PAD test as a development program under the terms of the strategic alliance agreement. Additionally, Vermillion has studies underway to detect early stage ovarian cancer, predict prognosis and recurrence, and identify women considered at high-risk for ovarian cancer.

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*Peripheral arterial disease.* This disease affects over 12 million Americans, which often goes undiagnosed and untreated. The number of people diagnosed with PAD is expected to increase concurrently with the rising number of people diagnosed with diabetes. The absence of a good blood test contributes to PAD going undiagnosed. In collaboration with Stanford, Vermillion has performed both an initial discovery study and a first validation study that has resulted in the identification of two blood markers that could assist in the diagnosis of PAD. These findings form the basis of a novel blood diagnostic test for PAD.

The two blood markers are currently undergoing validation. The results of these studies, including the publication of two newly discovered blood markers for PAD, were published in the August 2007 on-line peer-reviewed journal *Circulation*, which is published by the American Heart Association. Ongoing efforts are aimed at further validating these biomarkers in combination with additional cardiovascular biomarkers. Quest has accepted the PAD test as a development program under the terms of the strategic alliance agreement.

Thrombotic thrombocytopenic purpura. This disease affects approximately 1,000 Americans annually and is life threatening in the absence of appropriate treatment, which is usually plasmaphoresis. Undertreatment can lead to increased mortality from the disease while overtreatment wastes precious resources. In addition, patients with TTP need to be monitored for clinical response to therapy. TTP is a result of absent or reduced levels, also known as a defect in the activity, of the ADAMTS13 enzyme. Mass spectrometry was used as a logical approach to develop an accurate and quantitative assay to measure this enzymatic activity. Vermillion completed the development of the TTP Assay, which has been validated at the OSU Reference Laboratory. OSU is now offering the diagnostic test for clinical use and is purchasing reagents from Vermillion.

*Prostate cancer.* Each year approximately 250,000 men are diagnosed with prostate cancer in the United States, approximately 195,000 of whom will need to make a critical decision on whether or not to undergo local therapy, such as surgery or radiation treatment, and on whether or not to have additional treatment after local therapy. There is also a need for a reliable test to determine the likelihood of progression and the likelihood of recurrence after local treatment.

In May 2006, Vermillion and JHU reported the discovery of two biomarkers that, when combined with prostate specific antigen (PSA), were highly predictive of likelihood of recurrence of prostate cancer. These findings resulted from two studies, one examining over 400 men with prostate cancer, and the other examining 50 pairs of men followed for 5 years with prostate cancer matched for age, cancer stage and other clinical parameters. These results suggest the potential of a test to aid in the stratification of risk of highly aggressive prostate cancer independent of other clinical variables, reduce over treatment of prostate cancer cases not likely to be lethal and shift treatment to those cases that are particularly likely to be lethal.

Breast cancer. Detection of early stage breast cancer holds the potential to improve outcomes for women with this disease. No blood markers currently exist that can accurately detect ductal carcinoma in situ (DCIS), which is one of the earliest stages of breast cancer, and it is likely that imaging modalities such as mammography, ultrasound and magnetic resonance imaging will improve detection accuracy when combined with blood markers or molecular imaging targets. In collaboration with JHU, Vermillion has performed two independent studies to identify blood markers for DCIS and stage I breast cancer. The first study examined 169 women who were healthy, in benign disease and in varying stages of breast cancer. The second study examined 176 women from a different medical center as independent validation. Vermillion is currently performing a 350 woman multi-center validation study to confirm the two biomarkers identified in the previous studies.

Liver cancer. Individuals infected with the hepatitis virus are at increased risk of developing hepatic fibrosis that progresses to cirrhosis and eventually to hepatocellular carcinoma (HCC). Alpha fetoprotein (AFP) is a biomarker for HCC with limited sensitivity and specificity. In collaboration with UTMB, Vermillion is evaluating a multi-biomarker panel that may identify individuals at increased risk of HCC.

## Commercialization

If Vermillion is successful at discovering biomarkers and panels of biomarkers that have diagnostic utility, our commercialization strategy focuses on partnering with other parties to assist in the development and

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commercialization of Vermillion s initial tests. On July 22, 2005, Vermillion entered into a three-year strategic alliance agreement with Quest to develop and commercialize up to three diagnostic tests.

Vermillion expects to commercialize and sell diagnostic tests in one or both of two phases. The first phase, referred to as the analyte specific reagent (ASR) phase, will involve the sale of ASRs to certain customers coupled with the grant to such customer of a sublicense to perform the ASR laboratory test using the methodology covered by the relevant license obtained from Vermillion s collaborators, such as a test for ovarian cancer covered by licenses from JHU and M.D. Anderson. ASRs are the raw materials Vermillion will resell or make itself, and are 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). During the second phase, or IVD phase, Vermillion plans to assemble and sell IVD test kits, which have been cleared by the FDA, to customers together with SELDI instruments.

Under this strategic alliance agreement, Quest has the exclusive right to perform up to three ASR laboratory tests. Upon obtaining FDA clearance, Vermillion will begin manufacturing IVD test kits that Quest will purchase. Quest will have the exclusive right for up to five years, following commercialization of each respective diagnostic test kit (the Exclusive Period ), to perform such ASR laboratory tests and market IVD test kits purchased from Vermillion in the United States, Mexico, the United Kingdom and other countries where Quest operates a clinical laboratory, and non-exclusive rights to commercialize these diagnostic test kits in the rest of the world, subject to a royalty payable to Vermillion.

During the ASR phase for a given ASR laboratory test, and as long as the Exclusive Period continues, Vermillion will sell ASRs and grant rights to perform such ASR laboratory tests to Quest and other reference laboratories, hospitals and medical clinics in countries where Quest does not operate a clinical laboratory. Once the IVD phase begins for a given ASR laboratory test in the Exclusive Period, the Company will sell IVD test kits and SELDI instruments to Quest. At the end of the Exclusive Period with respect to any IVD test kit, Quest—s exclusive right to perform ASR laboratory tests using such diagnostic test kits will become non-exclusive. In addition to continuing to sell IVD test kits to Quest, the Company will also sell IVD test kits to commercial clinical laboratories in the United States, Mexico, the United Kingdom and other countries, which were exclusive to Quest during the Exclusive Period. In addition to working through Quest, Vermillion intends to seek partnerships for commercialization purposes with traditional IVD companies and/or with clinical reference labs in territories where Quest does not have exclusive rights.

#### **Customers**

We believe a substantial portion of all sales of diagnostic products are made to a small number of clinical reference laboratories such as Quest and Laboratory Corporation of America. Accordingly, we expect Quest, other reference laboratories, future commercialization partners, hospitals and medical clinics that perform diagnostic testing will provide a substantial portion of the Company s revenue.

#### **Research and Development**

Vermillion s research and development efforts towards developing novel diagnostic tests focus on two synergistic activities; (1) developing new approaches to investigate the human proteome and (2) utilizing new technologies to discover biomarkers that can address unmet clinical needs. A major area of Vermillion s research and development activities centers on efforts to discover and validate biomarkers and patterns of biomarkers that can be developed into diagnostic assays. Vermillion does this both through in-house programs and through collaborations it has established with JHU, M.D. Anderson and Stanford among others.

In applied research, Vermillion is developing new applications and reagents for quantitative differential protein expression analysis, protein interaction assays and protein characterization. Vermillion s efforts are particularly

focused on discovery and quantitative analysis of low-abundance proteins present in complex samples such as plasma, serum and urine. Vermillion has demonstrated that the surface chemistries immobilized on ProteinChip Arrays have similar protein selectivity to those chemistries immobilized on higher capacity bead formats, facilitating the transition from discovery on arrays to small-scale purification on beads as well as orthogonal purification. Using these approaches, Vermillion seeks to improve the speed and efficiency of designing protein

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separation strategies at any scale based on the predictive information obtained using ProteinChip Systems. We believe these methods will accelerate the identification of discovered biomarkers.

Vermillion s activities in research and development will focus on protein separation technologies, particularly on the development or clinical assays (i.e., taking research tools and developing them into practical, usable tools for biomarker discovery and assay). Research will initially focus on three major tasks:

Provide methodologies for making bead technologies based on combinatorial ligand libraries for low-abundance protein enrichment practical for biomarker discovery;

Provide methodologies for making othorgonal chromatographic separation of proteomes in a simplified serial workflow practical for biomarker discovery; and

Develop clinical assays using novel proteomics technologies.

The achievement of these objectives will help Vermillion gain a competitive edge in biomarker discovery, enhance its ability to improve the current diagnostic tests under development as well as to develop a pipeline of diagnostic tests. Vermillion s new proteomic analysis tools are intended to provide it with an important advantage in the race to discover novel biomarkers. The complexity of the human proteome has hindered efforts to develop a comprehensive database of expressed proteins and their post-translational modifications. Vermillion has focused on developing solutions to the problem of separating proteins to increase the number of proteins that can be detected and characterized while maintaining the throughput necessary to run sufficient clinical samples to achieve statistical significance. These novel solutions are embodied in Vermillion s proprietary technology such as equalizer beads and multi-select and mini-select technologies. These tools are being applied to clinical assay development in oncology, hematology, cardiology and women s health. The Company s research and development expenses were \$8,213,000 and \$11,474,000 for the years ended December 31, 2007 and 2006, respectively.

#### **Intellectual Property**

Vermillion s intellectual property includes a portfolio of owned, co-owned or licensed patents and patent applications. As of December 31, 2007, Vermillion s patent portfolio included 53 issued United States patents, 94 pending United States patent applications, and numerous pending patent applications and issued patents outside the United States. These patents and patent applications are directed to several areas of technology important to Vermillion s business, including SELDI technology, diagnostic applications, protein biochips, instrumentation, software and biomarkers. The issued patents covering the SELDI and mass spectrometry technologies expire at various times from 2012 to 2025. Pursuant to the Instrument Business Sale, the Company entered into a cross license agreement with Bio-Rad pursuant to which the Company retained the right to commercially exploit those proprietary rights, including SELDI technology, in the clinical diagnostics market. The clinical diagnostics market includes laboratories engaged in the research and development and/or manufacture of diagnostic tests using biomarkers, commercial clinical laboratories, hospitals and medical clinics that perform diagnostic tests. The Company has been granted exclusive rights to commercialize the proprietary rights in the clinical diagnostics market during a five-year exclusivity period that ends on November 13, 2011. After the end of the five-year period, the Company and Bio-Rad will share exclusive rights. 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.

Vermillion owns, licenses or hold options to license the patents related to biomarkers developed using SELDI technology. As of December 31, 2007, 33 of Vermillion s patent applications are directed to biomarker inventions and 6 are dedicated to other diagnostic applications. These include applications in the areas of cancer, cardiovascular disease, infectious disease, neurodegenerative disease and women s health. Vermillion has negotiated an extension of

the term of its collaboration agreement with JHU, which ends on December 31, 2010, with automatic one-year extensions for up to three additional years unless terminated by Vermillion or JHU, to patent applications directed to biomarkers for ovarian cancer that Vermillion intends to commercialize as an ovarian cancer diagnostic test. Other institutions and companies from which Vermillion holds options to license intellectual property related to biomarkers include UCL, M.D. Anderson, University of Kentucky, OSU, McGill University (Canada), Eastern Virginia Medical School, Aaron Diamond AIDS Research Center, UTMB, Goteborg University (Sweden), University of Kuopio (Finland) and The Katholieke Universiteit Leuven (Belgium).

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The rights to the SELDI technology are derived through royalty-bearing sublicenses from Molecular Analytical Systems, Inc. (MAS). MAS holds an exclusive license to patents directed to the SELDI technology from the owner, Baylor College of Medicine. MAS granted certain rights under these patents to its wholly owned subsidiaries, IllumeSys Pacific, Inc. and Ciphergen Technologies, Inc. in 1997. Vermillion obtained further rights under the patents in 2003 through sublicenses and assignments executed as part of the settlement of a lawsuit between Vermillion, MAS, LumiCyte and T. William Hutchens. Together, the sublicenses and assignments provide all rights to develop, make and have made, use, sell, import, market and otherwise exploit products and services covered by the patents throughout the world in all fields and applications, both commercial and non-commercial. The sublicenses carry the obligation to pay MAS a royalty equal to 2% of revenues recognized between February 21, 2003, and the earlier of (i) February 21, 2013, or (ii) the date on which the cumulative payments to MAS have reached \$10,000,000 (collectively the Sublicenses). As of December 31, 2007, Vermillion has paid \$2,597,000 in royalties to MAS under the Sublicenses. In connection with the Instrument Business Sale, Vermillion sublicensed to Bio-Rad certain rights to the Sublicense for use outside of the clinical diagnostics field. Vermillion retained exclusive rights to the Sublicense for use in the field of clinical diagnostics for a five-year period, after which Vermillion will retain non-exclusive rights in that field. Bio-Rad agreed to pay the royalties directly to MAS under the Sublicense rights.

On July 10, 2007, Vermillion entered into a license and settlement agreement with Health Discovery Corporation (HDC) pursuant to which Vermillion licensed more than 25 patents covering HDC is support vector machine technology for use with SELDI technology. Under the terms of the HDC Agreement, Vermillion receives a worldwide, royalty-free, non-exclusive license for life sciences and diagnostic applications of the technology and has access to any future patents resulting from the underlying intellectual property in conjunction with use of SELDI systems. Pursuant to the HDC Agreement, Vermillion paid \$200,000 to HDC upon entry into the agreement on July 10, 2007, and \$100,000 three months following the date of the agreement on October 10, 2007. The remaining \$300,000 payable under the HDC Agreement is payable as follows: \$150,000 twelve months following the date of the agreement. The HDC Agreement settled all disputes between Vermillion and HDC.

#### **Manufacturing**

As a result of the Instrument Business Sale, Vermillion relies on Bio-Rad to manufacture and supply ProteinChip Systems and ProteinChip Arrays (collectively referred to herein as the Research Tools Products ), which were previously manufactured by the Company. Under the manufacture and supply agreement, Bio-Rad has agreed to manufacture and supply the Company with Research Tools Products. If Bio-Rad develops new products using SELDI technology, Bio-Rad has agreed to supply those products to the Company for resale to its customers. The Company can also request that Bio-Rad develop and manufacture new products to written specifications and will negotiate the terms in good faith to purchase such products. Additionally, under the manufacture and supply agreement, Vermillion has agreed to purchase from Bio-Rad the Research Tools Products required to support its diagnostics efforts. Vermillion has a commitment to purchase 10 systems and 30,000 arrays in the first year, 13 systems and 30,000 arrays in the second year, and 20 systems and 30,000 arrays for the third year in order to support its collaboration agreements with Quest and other collaborators, which may be used as inventory for resale, fixed assets for collaboration purposes or supplies for research and development. The Company has estimated the cost to be \$70,000 per system and \$40 per array. If Bio-Rad fails to supply any Research Tools Products to Vermillion, including any new products using SELDI technology developed by Bio-Rad or any new products Vermillion has requested Bio-Rad to make and sell to Vermillion, under certain conditions Vermillion has the right to manufacture or have a third party manufacture these products for Vermillion s own use and sale to its customers and collaborators in the clinical diagnostics market. The sale of these products manufactured by Vermillion or a third party is subject to a royalty to Bio-Rad. Vermillion is responsible for assuring, through its incoming quality control process, that the Research Tools Products purchased from Bio-Rad comply with applicable government regulations. Vermillion made total purchases of \$1,032,000 and \$38,000 under this agreement for the years ended December 31, 2007 and 2006, respectively. As of December 31,

2007, Vermillion had a total remaining first year obligation to purchase 4 systems and 13,098 arrays, or \$804,000 based the on estimated costs of \$70,000 per system and \$40 per array. As of December 31, 2007, the Company owed Bio-Rad \$246,000 for Research Tools Products.

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#### **Environmental Matters**

#### Medical Waste

Vermillion is 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. Vermillion s laboratory facility in Fremont, California is operated in material compliance with applicable federal and state laws and regulations relating to disposal of all laboratory specimens. Vermillion utilizes outside vendors for disposal of specimens. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. Vermillion could be subject to damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials.

#### **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, including clinical laboratories, 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.

#### Specimen Transportation

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

### **Government Regulation**

#### General

Vermillion s 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 there-under, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of its 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.

Generally, certain categories of medical devices, including a category that may be deemed to include potential future products based upon the ProteinChip platform, may require FDA 510(k) clearance, or 510(k) de novo clearance or pre-market approval (PMA). Although the FDA believes it has jurisdiction to regulate in-house laboratory tests, or home brews, that have been developed and validated by the laboratory providing the tests, the FDA has not, to date, actively regulated those tests. ASRs that are sold to laboratories for use in tests developed in-house by clinical laboratories generally do not require FDA approval or clearance. Most ASRs are Class I devices subject to general controls under Section 513(a)(1)(A) of the Federal Food, Drug and Cosmetic Act, but exempt from pre-market notification. ASR s may be (1) sold to clinical laboratories regulated under CLIA, as qualified to perform high complexity testing, or clinical laboratories regulated under Veterans Health Administration Directive 1106, (2) manufactured in compliance with the FDA s QSRs, and (3) labeled in accordance with FDA requirements under Title 21 of the Code of Federal Regulations Part, 820.30, including a statement that their analytical and performance characteristics have not been established. A similar statement would also be required on all advertising and

promotional materials relating to ASRs, such as those used in certain of its proposed future tests. However, the regulatory environment surrounding in vitro diagnostic multivariate index assays ( IVDMIAs ) is changing. IVDMIA devices, such as its ovarian cancer test, employ not only the data generated by ordinary ASRs but also an algorithm used to generate a result that is used in the prevention or treatment of disease. The FDA issued draft guidance in September 2006, which states that it will regulate IVDMIAs as class II or III devices, depending on the risk they present. Class II devices are subject to 510(k) notification and class III devices require clinical testing and a PMA. However, FDA draft guidance is not the law and does not operate to bind either the FDA or the public.

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Guidances reflect the FDA s current thinking about a subject and the position it will take when dealing with that subject. Accordingly, the current regulatory environment with regard to regulation of ASRs, and IVDMIAs in particular, is very unclear. It is possible that the FDA s current policy or future revisions to FDA policies may have the effect of increasing the regulatory burden on manufacturers of these devices.

Regardless of whether a medical device requires FDA approval or clearance, a number of other FDA requirements apply to the manufacturer of such a device and to those who distribute it. Device manufacturers must be registered and their products listed with the FDA, and certain adverse events, corrections and removals must be reported to the FDA. The FDA also regulates the product labeling, promotion and, in some cases, advertising of medical devices. Manufacturers must comply with the FDA s QSRs, which establish extensive requirements for design, quality control, validation and manufacturing. Thus, manufacturers and distributors must continue to spend time, money and effort to maintain compliance, and failure to comply can lead to enforcement action. The FDA periodically inspects facilities to ascertain compliance with these and other requirements.

#### Diagnostic Test Kits

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 premarket notification clearance, known as a 510(k) clearance or 510(k) de novo clearance, or a FDA PMA. Some of Vermillion s 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, Vermillion may not market a device until an order is issued by the FDA finding its 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 Vermillion products.

If the FDA indicates that a PMA is required for any of Vermillion 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.

Once granted, a 510(k) clearance or PMA approval may place substantial restrictions on how Vermillion s device is marketed or to whom it may be sold. Even in the case of devices like ASRs, which may be exempt from 510(k) clearance or PMA approval requirements, the FDA may impose restrictions on marketing. Vermillion s potential future ASR products may be sold only to clinical laboratories certified under 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. Vermillion cannot assure that any necessary 510(k) clearance or PMA approval will be granted on a timely basis, or at all. 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 Vermillion s products, could have a material adverse effect on the Company. As a medical device manufacturer, Vermillion is also required to register and list its products with the FDA. In addition, Vermillion is required to comply with the FDA s QSRs, which require that its devices be manufactured and records be maintained in a prescribed manner with respect to manufacturing, testing and control activities. Further, Vermillion is 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. In addition, the medical device

reporting regulation requires that Vermillion provides information to the FDA whenever evidence reasonably suggests that one of its 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.

Vermillion s suppliers manufacturing facilities are, and, if and when Vermillion begins commercializing and manufacturing its products itself, its manufacturing facilities will be, subject to periodic and unannounced

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inspections by the FDA and state agencies for compliance with QSRs. Additionally, the FDA will generally conduct a preapproval inspection for PMA devices. Although Vermillion believes it and its suppliers will be able to operate in compliance with the FDA s QSRs for ASRs, neither Vermillion nor its suppliers have ever been subject to a FDA inspection and cannot assure that Vermillion will be able to maintain compliance in the future. If the FDA believes that Vermillion or its 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 Vermillion products, issue a recall notice, enjoin future violations and assess civil and criminal penalties against Vermillion. In addition, approvals or clearances could be withdrawn under certain circumstances.

Any customers using Vermillion s products for clinical use in the United States may be regulated under CLIA. CLIA 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 the Company may do business outside the United States. These range from comprehensive device approval requirements for some or all of Vermillion—s 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).

## **Employees**

As of December 31, 2007, the Company had 30 full-time employees worldwide, including 5 in sales and marketing, 14 in research and development and 11 in general and administrative departments. The Company also had an additional 13 individuals engaged as independent contractors. None of the Company s employees are covered by a collective bargaining agreement. The Company believes that its relations with its employees are good. The Company s success will depend in large part on its ability to attract and retain skilled and experienced employees. In an effort to further streamline operations, the Company reduced its workforce by 9 employees during March 2008. As a result of the reduction in workforce, the Company had 19 employees as of March 31, 2008.

#### **Code of Ethics for Executive Officers**

The Company has adopted a Code of Ethics for Executive Officers. The Company publicizes the Code of Ethics for Executive Officers by posting the policy on its website, <a href="www.vermillion.com">www.vermillion.com</a>. The Company will disclose on its website any waivers of or amendments to its Code of Ethics for Executive Officers.

## **Information About Vermillion**

The Company files annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission (the SEC). You may read and copy any document the Company files at the SEC s Public Reference Rooms in Washington, D.C., New York, New York and Chicago, Illinois. The Public Reference Room in Washington, D.C. is located at 450 Fifth Street, N.W. Please call the SEC at 1-800-SEC-0330 for further information on the public conference rooms. The Company s SEC filings are also available to the public from the SEC s website at <a href="https://www.sec.gov.">www.sec.gov.</a>

In addition, the Company makes available free of charge the Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Reports on Form 8-K and amendments to those reports as soon as reasonably practicable after the reports have been electronically filed with or furnished to the SEC pursuant to the Section 13(a) or 15(d) of the

Securities Exchange Act of 1934 through the Company s website, <a href="www.vermillion.com">www.vermillion.com</a>, under Investor Relations . Paper copies of these documents may also be obtained free of charge by writing to Vermillion, Inc., Investor Relations, 6611 Dumbarton Circle, Fremont, CA 94555.

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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 Vermillion, Inc. (Vermillion), formerly known as Ciphergen Biosystems, Inc., and subsidiaries (collectively referred to as the Company) audited consolidated financial statements and the accompanying notes in Part II Item 8, Financial Statements and Supplementary Data. The risks and uncertainties management (we, us or our) describes below are the only ones the Company faces. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also adversely affect the Company s business.

## **Reverse Stock Split**

Vermillion had a 1 for 10 reverse stock split of Vermillion s common stock effective at the close of business on March 3, 2008. Accordingly, all share and per share amounts were adjusted to reflect the impact of the 1 for 10 reverse stock split in this Annual Report on Form 10-K.

## Risks Related to the Company s Business

We expect to continue to incur net losses in 2008. If we are unable to generate significant diagnostic products revenue, the Company may never achieve profitability.

From the Company s inception through December 31, 2007, the Company has generated cumulative revenue from the sale of products and services to customers of \$229,300,000 and has incurred net losses of \$239,142,000. The Company has experienced significant operating losses each year since its inception and we expect these losses to continue for at least the next several quarters, resulting in an expected net loss for the year ending December 31, 2008. For example, the Company experienced net losses of \$21,282,000 and \$22,066,000 for the years ended December 31, 2007 and 2006, respectively. The Company s losses have resulted principally from costs incurred in research and development, sales and marketing, litigation, and general and administrative costs associated with the Company s operations. These costs have exceeded the Company s gross profit, which was generated principally from product sales derived from protein research products and service income derived from the collaborative services business (the Instrument Business ). On November 13, 2006, the Company sold the assets and liabilities of the Instrument Business (the Instrument Business Sale ) to Bio-Rad Laboratories, Inc. (Bio-Rad). We expect to incur additional operating losses that may be substantial. The Company s failure to become and remain profitable may depress the market price of Vermillion s common stock and impair the Company s ability to raise capital and continue our operations. Even if the Company does achieve profitability, the Company may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We believe that the Company s current cash balances may not be sufficient to fund planned expenditures. This raises substantial doubt about the Company s ability to continue as a going concern. During 2008, we will need to raise additional funds through the issuance of equity or debt securities, or a combination thereof, in the public or private markets in order to continue operations. Additional financing opportunities may not be available, 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 the Company. Any future equity financing would result in substantial dilution to Vermillion s stockholders. If we raise additional funds by issuing debt, the Company may be subject to limitations on its operations, through debt covenants or other restrictions. If adequate and acceptable financing is not available, we may have to delay development or commercialization of certain Vermillion products or license to third parties the rights to

commercialize certain Vermillion products or technologies that we would otherwise seek to commercialize. We may also reduce the Company s marketing or other resources devoted to Vermillion s products. Any of these options could reduce our ability to successfully execute our business plan.

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Substantial leverage and debt service obligations may adversely affect the Company s consolidated cash flows.

As of December 31, 2007, Vermillion had \$19,000,000 of convertible senior notes outstanding and \$10,000,000 outstanding under Vermillion s secured line of credit with Quest Diagnostics Incorporated (Quest). As a result of this indebtedness, the Company has high principal and interest payment obligations. The degree to which the Company is leveraged could, among other things:

make it difficult for the Company to make payments on the convertible senior notes and secured line of credit;

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

make the Company more vulnerable to industry downturns and competitive pressures; and

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

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

The Company holds auction rate securities in its portfolio of investments. Due to failed auctions for some of the Company's auction rate investments through March 24, 2008, the Company is currently unable to liquidate its auction rate securities into cash. If the Company is unable to liquidate its investments in auction rate securities within the next several months, other financing sources will be required in order to continue operations.

At December 31, 2007, the Company s investments consisted of \$12,777,000 invested in auction rate securities, including \$3,902,000 classified as available-for-sale long-term investments as a result of certain auction rate securities failing to settle at auctions subsequent to December 31, 2007.

As of March 24, 2008, the Company s entire investment portfolio of \$6,500,000 was invested in auction rate securities, which failed to settle at auctions from January 1, 2008, to March 24, 2008, due to the current overall credit concerns in the United States capital markets, and are classified as available-for-sale long-term investments. The investment portfolio at March 24, 2008, consists of \$3,902,000 of auction rate securities classified as available-for-sale long-term investments at December 31, 2007, and an additional \$2,500,000 of auction rate securities purchased during January and February 2008, which failed to settle at auctions during March 2008. These auction rate securities provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, which is generally every 28 days. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security, which rate is generally higher than the current market rate. The failure of the auctions means the Company may be unable to liquidate its auction rate securities into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument. If the Company is unable to liquidate its investments in auction rate securities or there is an other-than-temporary impairment in the market value of its investments in auction rate securities, this will have an adverse affect on the Company s business, consolidated results of operations, financial condition and cash flows, and may increase the volatility of Vermillion s common stock price. In addition, if the Company is unable to liquidate its investments in auction rate securities or borrow against these investments within the next several months, the Company will require other financing sources in order to continue operations, and there can be no assurance that other funding sources will be available.

The Company may not succeed in developing diagnostic products and even if the Company does succeed in developing diagnostic products, the diagnostic products may never achieve significant commercial market acceptance.

The Company s success depends on our ability to develop and commercialize diagnostic products. There is considerable risk in developing diagnostic products based on Vermillion s biomarker discovery efforts as potential tests may fail to validate results in larger clinical studies and may not achieve acceptable levels of clinical sensitivity and specificity. If we do succeed in developing diagnostic tests with acceptable performance characteristics, we may not succeed in achieving significant commercial market acceptance for those tests. Our ability to successfully commercialize diagnostic products that Vermillion may develop, such as tests, kits and devices, will depend on several factors, including:

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

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

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

These factors present obstacles to significant commercial acceptance of Vermillion s potential diagnostic products, which we will have to spend substantial time and the Company s financial resources to overcome, if we can do so at all. Our inability to successfully do so would prevent the Company from generating revenue from diagnostic products and from developing a profitable business.

# Our ability to commercialize Vermillion s potential diagnostic tests is heavily dependent on its strategic alliance with Ouest.

On July 22, 2005, Vermillion and Quest entered into a strategic alliance, which focuses on commercializing up to three diagnostic tests chosen from Vermillion spipeline. The term of the agreement ends on the later of (i) the three-year anniversary of the agreement and (ii) the date on which Quest commercializes the three diagnostic tests covered by such agreement. If this strategic alliance does not continue for its full term or if Quest fails to proceed to diligently perform its obligations as a part of the strategic alliance, such as independently developing, validating, and commercializing potential diagnostic tests, our ability to commercialize Vermillion spotential diagnostic tests would be seriously harmed. Due to the current uncertainty with regard to United States Food and Drug Administration (the FDA) regulation of analyte specific reagents (ASRs) or, for other reasons, Quest may elect to forgo development of ASR home brew laboratory tests and instead elect to wait for the development of in vitro diagnostic (IVD) test kits, which would adversely affect the Company s revenues. If we elect to increase the Company s expenditures to fund in-house diagnostic development programs or research programs, the Company will need to obtain additional capital, which may not be available on acceptable terms, or at all.

#### The commercialization of Vermillion's diagnostic tests may be adversely affected by changing FDA regulations.

The current regulatory environment with regard to ASRs and in vitro diagnostic multivariate index assays ( IVDMIAs ) in particular, such as Vermillion s potential ovarian cancer diagnostic test, is very unclear. To the extent the FDA requires that Vermillion s potential diagnostic tests receive FDA 510(k) clearance or FDA pre-market approval, our ability to develop and commercialize Vermillion s potential diagnostic tests may be prevented or significantly delayed,

which would adversely affect the Company s consolidated revenues, results of operations and financial condition.

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

Vermillion s 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 Vermillion s product offerings. Development of these technologies remains a substantial risk to the Company due to various factors, including the scientific challenges involved, our ability to find and collaborate with others working in the diagnostic field, and competing technologies, which may prove more successful than Vermillion s technologies. In addition, we have reduced Vermillion s research and development headcount and expenditures, which may adversely affect Vermillion s ability to further develop its technologies.

If we fail to maintain Vermillion s rights to utilize intellectual property directed to diagnostic biomarkers, Vermillion 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 Vermillion has the right to utilize through licenses with its academic collaborators, such as The Johns Hopkins University School of Medicine and The University of Texas M.D. Anderson Cancer Center. In some cases, Vermillion s collaborators own the entire right to the biomarkers. In other cases, Vermillion co-owns the biomarkers with its collaborators. If, for some reason, Vermillion loses its license to biomarkers owned entirely by its collaborators, Vermillion may not be able to use those biomarkers in diagnostic tests. If Vermillion loses its exclusive license to biomarkers co-owned by Vermillion and its collaborators, Vermillion s collaborators may license their share of the intellectual property to a third party that may compete with the Company in offering diagnostic tests, which would materially adversely affect the Company s consolidated revenues, results of operations and financial condition.

Vermillion has drawn \$10,000,000 from the secured line of credit provided by Quest. If Vermillion fails to achieve the milestones for the forgiveness of the secured line of credit set forth therein, Vermillion will be responsible for full repayment of the secured line of credit.

As of December 31, 2007, Vermillion has drawn \$10,000,000 from the secured lined of credit in connection with the strategic alliance with Quest. Vermillion borrowed in monthly increments of \$417,000 over a two-year period, and made monthly interest payments. Funds from this secured line of credit may only be used for certain costs and expenses directly related to the strategic alliance, with forgiveness of the repayment obligations based upon Vermillion s achievement of milestones related to the development, regulatory approval and commercialization of certain diagnostic tests. Should Vermillion fail to achieve these milestones, Vermillion would be responsible for the repayment of the outstanding principal amount and any unpaid interest on the secured line of credit on or before July 22, 2010, which would materially adversely affect the Company s consolidated results of operations and financial condition.

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

The Company s success depends in part on our ability to maintain and enforce Vermillion s proprietary rights. The Company relies on a combination of patents, trademarks, copyrights and trade secrets to protect Vermillion s technology and brand. In addition to Vermillion s licensed SELDI technology, Vermillion has also submitted patent applications covering biomarkers that may have diagnostic or therapeutic utility. Vermillion s patent applications may not result in additional patents being issued.

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

The Company also relies upon the skills, knowledge and experience of its technical personnel. To help protect Vermillion s rights, we require all employees and consultants to enter into confidentiality agreements that prohibit

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the disclosure of confidential information. These agreements may not provide adequate protection for the Company s 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 materially adversely affect on the Company s business and consolidated results of operations and financial condition.

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

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

## Current and future litigation against the Company could be costly and time consuming to defend.

The Company is from time to time subject to legal proceedings and claims that arise in the ordinary course of business, such as claims brought by the Company s 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, the Company may bring claims against third parties for infringement on Vermillion s intellectual property rights. Litigation may result in substantial costs and may divert our attention and Company resources, which may seriously harm the Company s business, consolidated results of operations and consolidated financial condition.

An unfavorable judgment against the Company in any legal proceeding or claim could require the Company 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 Vermillion s licensing and sublicensing activities, which could harm the Company s business, consolidated results of operations and consolidated financial condition.

On September 17, 2007, Molecular Analytical Systems (MAS) filed a lawsuit naming Vermillion and Bio-Rad as defendants. Under the lawsuit, MAS seeks an unspecified amount of damages and alleges, among other things, under the lawsuit, among other things, that Vermillion is in breach of its license agreement with MAS relating to SELDI technology as a result of Vermillion s entry into a sublicense agreement with Bio-Rad. Vermillion s deadline to answer or otherwise respond to the Complaint is April 1, 2008. Vermillion intends to vigorously defend this action. Given the early stage of this action, we cannot predict the ultimate outcome of this matter at this time.

Vermillion depends on a single supplier to manufacture and supply its products and any interruption in this supplier relationship could materially and adversely affect the Company s consolidated revenues, results of operations and financial condition.

In connection with the Instrument Business Sale, Vermillion entered into a manufacture and supply agreement with Bio-Rad, pursuant to which Bio-Rad manufactures and supplies Vermillion with SELDI instruments and consumables (SELDI Products). The initial term of the agreement expires on November 12, 2011, and is renewable for two additional two-year terms. If the manufacture and supply agreement is terminated or is not renewed, or if Bio-Rad ceases manufacturing the SELDI Products for another reason, Vermillion would have to find another third party supplier to manufacture and supply the SELDI Products or begin manufacturing and supplying the SELDI Products itself. The Company or another third-party supplier may not be able to produce those products at a cost that is

available to Bio-Rad, or at the quantities or quality similar to Bio-Rad. Any such interruption could delay or diminish the Company s ability to satisfy its customers orders and adversely affect the Company s

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relationship with its customers. Additionally, any such interruption may have a material and adverse affect the Company s consolidated revenues, results of operations and financial condition.

The Company s failure to meet its purchase commitments pursuant to a manufacture and supply agreement with Bio-Rad, could adversely affect the Company s consolidated financial condition and results of operation.

Vermillion is a party to a manufacture and supply agreement with Bio-Rad, dated November 13, 2006, whereby Vermillion agreed to purchase from Bio-Rad the ProteinChip Systems and ProteinChip Arrays necessary to support Vermillion s diagnostics efforts. Under the terms of the agreement, Vermillion is required to purchase a specified number of ProteinChip Systems and ProteinChip Arrays in each of the three years following the date of the agreement. The Company has estimated its total obligation under the agreement to be \$6,610,000. As of December 31, 2007, Vermillion had an estimated purchase obligation of \$804,000 remaining with respect to the first year of the agreement. If Vermillion fails to renegotiate its initial purchase commitment under the agreement, it may need to make additional provisions for excess inventory, which would have an adverse affect on the Company s financial condition and results of operations. Furthermore, if future demand declines such that Vermillion cannot meet its minimum purchase requirements for 2008 and 2009, the Company s excess inventory could increase, thereby exacerbating the negative effect on the Company s financial condition and results of operations.

If the Company or its suppliers fail to comply with FDA requirements, the Company may not be able to market its products and services and may be subject to stringent penalties; further improvements to the Company s or its suppliers manufacturing operations may be required that would entail additional costs.

The commercialization of Vermillion s products could be affected by being delayed, halted or prevented by applicable FDA regulations. If the FDA were to view any of the Company s actions as non-compliant, it could initiate enforcement actions, such as a warning letter and possible imposition of penalties. In addition, ASRs that Vermillion may provide will be subject to a number of FDA requirements, including compliance with the FDA s Quality System Regulations (QSRs), 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 Vermillion or its potential suppliers. Adverse FDA actions in any of these areas could significantly increase the Company s expenses and limit its revenue and profitability. Although the Company is ISO 9001:2000 certified with respect to its manufacturing processes used for the Company s previous ProteinChip products, Vermillion will need to undertake additional steps to maintain its operations in line with the FDA QSR requirements. Vermillion s suppliers manufacturing facilities will be subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. If and when Vermillion begins commercializing and assembling its products itself, Vermillion s facilities will be subject to the same inspections. Vermillion or its suppliers may not satisfy such regulatory requirements, and any such failure to do so would have an adverse effect on Vermillion s diagnostics efforts.

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

The Company is highly dependent on its executive officers and certain key employees. Effective November 1, 2007, the Chief Financial Officer resigned from the Company for personal reasons. Upon the Chief Financial Officer s resignation from the Company, the Company s Corporate Controller was appointed to serve as Chief Financial Officer on an interim basis while the Company searches for a new Chief Financial Officer. As of March 31, 2008, the Company had 19 employees. The very lean staff and the absence of a permanent Chief Financial Officer and the loss of service of any other executive officers or certain key employees could impact operations or delay or curtail Vermillion s research, development and commercialization objectives. To continue Vermillion s research and product development efforts, the Company needs people skilled in areas such as bioinformatics, biochemistry and information services. Competition for qualified employees is intense.

## Vermillion s diagnostic efforts may cause it to have significant product liability exposure.

The testing, manufacturing and marketing of medical diagnostic tests entails an inherent risk of product liability claims. Potential product liability claims may exceed the amount of the Company s insurance coverage or may be excluded from coverage under the terms of the policy. The Company s existing insurance will have to be increased in the future if the Company is successful at introducing diagnostic products and this will increase the Company s costs. In the event that the Company is held liable for a claim against which it is not indemnified or for damages exceeding the limits of the Company s insurance coverage, the Company may be require to make substantial payments. This may have an adverse affect the Company s consolidated results of operations, financial condition and cash flows, and may increase the volatility of Vermillion s common stock price.

## Business interruptions could limit the Company s ability to operate its business.

The Company s operations, as well as those of the collaborators on which the Company depends, are vulnerable to damage or interruption from fire, natural disasters, computer viruses, human error, power shortages, telecommunication failures, international acts of terror and similar events. The Company s primary facility is located in Fremont, California, where it also has laboratories. Although we have certain business continuity plans in place, we have not established a formal comprehensive disaster recovery plan, and the Company s back-up operations and business interruption insurance may not be adequate to compensate it for losses the Company may suffer. A significant business interruption could result in losses or damages incurred by the Company and require the Company to cease or curtail its operations.

# Legislative actions resulting in higher compliance costs are likely to adversely affect the Company's 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, new Securities and Exchange Commission (the SEC) regulations and NASDAQ listing requirements, are resulting in increased compliance costs. The Company, like all other public companies, is incurring expenses and diverting employees—time in an effort to comply with Section 404 of the Sarbanes-Oxley Act of 2002. The Company is a smaller reporting company, and has completed the process documentation of its systems of internal control and has evaluated its systems of internal control. The Company is required to assess its compliance with Section 404 of the Sarbanes-Oxley Act of 2002 for the year ending December 31, 2007. We expect to devote the necessary resources, including additional internal and supplemental external resources, to support the Company s assessment. In the future, if we identify one or more material weaknesses, or the Company s independent registered public accounting firm is unable to attest that our report is fairly stated or to express an opinion on the effectiveness of the Company s internal controls, this could result in a loss of investor confidence in the Company s financial reports, have an adverse effect on Vermillion s stock price and/or subject the Company to sanctions or investigation by regulatory authorities. Compliance with these evolving standards will result in increased general and administrative expenses and may cause a diversion of our time and attention from revenue-generating activities to compliance activities.

#### The Company is subject to environmental laws and potential exposure to environmental liabilities.

The Company is subject to various international, federal, state and local environmental laws and regulations that govern the Company s operations, including the handling and disposal of nonhazardous 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. The Company is 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 of remediating 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

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that such costs and liabilities have not had and will not have a material adverse impact on the Company s consolidated results of operations.

## Risks Related to Owning Vermillion s Stock

Vermillion s principal stockholders own a significant percentage of Vermillion s outstanding common stock, and will continue to be able to exercise significant influence over the Company s affairs.

As of December 31, 2007, Quest possessed voting power over 860,595 shares, or 13.49%, and Phronesis Partners, L.P. (Phronesis), possessed voting power over 666,568 shares, or 10.45%, of Vermillion s outstanding common stock. As a result, Quest and Phronesis are able to determine a significant part of the composition of Vermillion s Board of Directors, hold significant voting power with respect to matters requiring stockholder approval and to exercise significant influence over the Company s operations. The interests of Quest and Phronesis may be different than the interests of other stockholders on these and other matters. This concentration of ownership also could have the effect of delaying or preventing a change in the Company s control or otherwise discouraging a potential acquirer from attempting to obtain control of the Company, which could reduce the price of Vermillion s common stock.

Vermillion currently does not meet and there is no guarantee that Vermillion will meet the standards for continued listing on the NASDAQ Capital Market, and if Vermillion is delisted the value of your investment in Vermillion may substantially decrease.

On February 22, 2008, Vermillion was notified by NASDAQ Listing Qualifications that it did not comply with Marketplace Rule 4310(c)(3) for continued inclusion as a result of the market value of Vermillion common stock falling below \$35,000,000 for 10 consecutive business days, and as required by Marketplace Rule 4310(c)(8)(C), Vermillion had 30 days, or until March 24, 2008, to regain compliance. Vermillion did not regain compliance by March 24, 2008, and, accordingly, on March 25, 2008, Vermillion received written notification from NASDAQ Listing Qualifications (the Staff Determination Notice) that Vermillion is securities would be subject to delisting as a result of the deficiency unless Vermillion requests a hearing before a NASDAQ Listing Qualifications Panel. The Company plans to timely request a hearing before the NASDAQ Listing Qualifications Panel to address the market value of listed securities deficiency, which will stay any action with respect to the Staff Determination Notice until the NASDAQ Listing Qualifications Panel renders a decision subsequent to the hearing. Vermillion anticipates that the hearing will be scheduled to occur within the next 45 days. There can be no assurance that the Panel will grant Vermillion is request for continued listing.

There is no guarantee that Vermillion will continue to meet the standards for listing in the future. Upon delisting from the NASDAQ Capital Market, Vermillion s common stock would be traded over-the-counter (OTC). OTC transactions involve risks in addition to those associated with transactions in securities traded on the NASDAQ Capital Market. Many OTC stocks trade less frequently and in smaller volumes than NASDAQ listed stocks. Accordingly, delisting from the NASDAQ Capital Market would adversely affect the trading price of Vermillion s common stock, significantly limit the liquidity of Vermillion s common stock and impair the Company s ability to raise additional funds.

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

Vermillion s certificate of incorporation, bylaws and stockholder rights plan contain provisions that could make it more difficult for a third party to acquire the Company, even if doing so might be deemed beneficial by Vermillion s stockholders. These provisions could limit the price that investors might be willing to pay in the future for shares of Vermillion s common stock. Vermillion is also subject to certain provisions of Delaware law that could delay, deter or

prevent a change in control of the Company. The rights issued pursuant to Vermillion s stockholder rights plan will become exercisable the tenth day after a person or group announces acquisition of 15% or more of Vermillion s common stock or announces commencement of a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of Vermillion s common stock. If the rights become exercisable, the holders of the rights (other than the person acquiring 15% or more of Vermillion s common

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stock) will be entitled to acquire, in exchange for the rights exercise price, shares of Vermillion common stock or shares of any company in which the Company is merged, with a value equal to twice the rights exercise price.

Because we do not intend to pay dividends, Vermillion s stockholders will benefit from an investment in Vermillion s 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 the Company s future earnings, if any, to finance the expansion of the Company s business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in Vermillion s common stock will depend entirely upon any future appreciation. There is no guarantee that Vermillion s common stock will appreciate in value or even maintain the price at which its investors purchased their shares.

Vermillion s stock price has been highly volatile, and an investment in Vermillion s stock could suffer a decline in value.

The trading price of Vermillion s 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 the Company s control, including:

failure to commercialize diagnostic tests and significantly increase revenue;

actual or anticipated period-to-period fluctuations in financial results;

failure to achieve, or changes in, financial estimates by securities analysts;

announcements or introductions of new products or services or technological innovations by the Company or its competitors;

publicity regarding actual or potential discoveries of biomarkers by others;

comments or opinions by securities analysts or major stockholders;

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

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

developments regarding Vermillion s patents or other intellectual property or that of the Company s competitors;

litigation or threat of litigation;

additions or departures of key personnel;

sales of Vermillion common stock;

limited daily trading volume;

delisting from the NASDAQ Capital Market; and

economic and other external factors, disasters or crises.

In addition, the stock market in general, and the NASDAQ Capital Market and the market for technology companies, in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been significant volatility in the market prices of securities of life science companies. These broad market and industry factors may seriously harm the market price of Vermillion common stock, regardless of the Company s 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 Vermillion could result in substantial costs, potential liabilities and the diversion of our attention and Company resources.

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The Company may need to sell additional shares of Vermillion common stock or other securities to meet the Company s capital requirements. If the Company needs to sell additional shares of Vermillion common stock or other securities to meet the Company s capital requirements, or upon conversion of the Company s senior convertible notes and exercises of currently outstanding options and warrants, the ownership interests of Vermillion s current stockholders could be substantially diluted. The possibility of dilution posed by shares available for future sale could reduce the market price of Vermillion s common stock and could make it more difficult for the Company to raise funds through equity offerings in the future.

As of December 31, 2007, Vermillion had 6,380,197 shares of common stock outstanding and 8,150,006 shares of common stock reserved for future issuance to employees, Directors and consultants pursuant to the Company s employee stock plans, of which 469,675 shares of common stock were subject to outstanding options. In addition, as of December 31, 2007, warrants to purchase 2,293,147 shares of common stock were outstanding at exercise prices ranging from \$9.25 to \$25.00 per share, with a weighted average exercise price of \$10.79 per share. In addition, there are 27,208 shares of common stock reserved for issuance upon conversion of Vermillion s outstanding 4.5% convertible senior notes due September 1, 2008, and 825,000 shares of common stock reserved for issuance upon conversion of Vermillion s 7.0% convertible senior notes due September 1, 2011. The exercise or conversion of all or a portion of these securities would dilute the ownership interests of Vermillion s stockholders. Furthermore, future sales of substantial amounts of Vermillion s common stock in the public market, or the perception that such sales are likely to occur, could affect prevailing trading prices of Vermillion s common stock and the value of the notes.

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## Item 1B. Unresolved Staff Comments

None

## Item 2. Properties

Vermillion, Inc. ( Vermillion ) and subsidiaries (collectively the Company ) principal facility is located in Fremont, California. The location, size and designated use of each facility that the Company leases as of December 31, 2007, are as follows:

Location	Approximate Square Feet	Primary Function	Lease Expiration Date
Fremont, California	61,000(1)	Research and development laboratories, marketing, sales and administrative offices	July 31, 2008
Galveston, Texas	500	Diagnostic test development laboratory	August 31, 2009

(1) Approximately 29,000 square feet of this space has been subleased to Bio-Rad Laboratories, Incorporated for the remaining lease term.

Vermillion s management ( we ) is actively reviewing all of the Company s space needs with intentions to reduce the Company s overall facilities expenses. Actions we may take include not renewing certain leases upon their expiration as well as seeking to sublease space to others.

#### Item 3. Legal Proceedings

On June 26, 2006, Health Discovery Corporation (HDC) filed a lawsuit against Vermillion, Inc. (Vermillion; Vermillion and its wholly-owned subsidiaries are collectively referred to as the Company ), formerly known as Ciphergen Biosystems, Inc., in the United States District Court for the Eastern District of Texas, Marshall Division (the Court ), claiming that software used in certain Vermillion ProteinChip Systems infringes on three of its United States patents. HDC sought injunctive relief as well as unspecified compensatory and enhanced damages, reasonable attorney s fees, prejudgment interest and other costs. On August 1, 2006, Vermillion filed an unopposed motion with the Court to extend the deadline for Vermillion to answer or otherwise respond until September 2, 2006. Vermillion filed its answer and counterclaim to the complaint with the Court on September 1, 2006. Concurrent with its answer and counterclaims, Vermillion filed a motion to transfer the case to the Northern District of California. On January 10, 2007, the Court granted Vermillion s motion to transfer the case to the Northern District of California. The parties met for a scheduled mediation on May 7, 2007. On July 10, 2007, Vermillion entered into a license and settlement agreement with HDC (the HDC Agreement ) pursuant to which it licensed more than 25 patents covering HDC s support vector machine technology for use with Surface Enhanced Laser Desorption/Ionization ( SELDI ) technology. Under the terms of the HDC Agreement, Vermillion receives a worldwide, royalty-free, non-exclusive license for life sciences and diagnostic applications of the technology and it has access to any future patents resulting from the underlying intellectual property in conjunction with use of SELDI systems. Pursuant to the HDC Agreement, Vermillion paid to HDC \$200,000 upon entry into the agreement on July 10, 2007, and \$100,000 three months following the date of the agreement on October 10, 2007. The remaining \$300,000 under the HDC Agreement is payable as follows: \$150,000 twelve months following the date of the agreement and \$150,000 twenty-four months

following the date of the agreement. The HDC Agreement settled all disputes between Vermillion and HDC.

On September 17, 2007, Molecular Analytical Systems (MAS) filed a lawsuit in the Superior Court of California for the County of Santa Clara naming Vermillion and Bio-Rad Laboratories, Inc (Bio-Rad) as defendants. Under the lawsuit, MAS seeks an unspecified amount of damages and alleges, among other things, that Vermillion is in breach of its license agreement with MAS relating to SELDI technology as a result of Vermillion s entry into a sublicense agreement with Bio-Rad. In connection with the sale of assets and liabilities of the protein research products and collaborative services business to Bio-Rad on November 13, 2006, Vermillion sublicensed to Bio-Rad certain rights to the SELDI technology that Vermillion obtained under the MAS license for use outside of

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the clinical diagnostics field. Vermillion retained exclusive rights to the technology for use in the field of clinical diagnostics for a five-year period, after which it will retain nonexclusive rights in that field. Vermillion s deadline to answer or otherwise respond to the Complaint is April 1, 2008. Vermillion intends to vigorously defend this action. Given the early stage of this action, management cannot predict the ultimate outcome of this matter at this time.

In addition, from time to time, the Company is involved in legal proceedings and regulatory proceedings arising out of its operations. Other than as disclosed above, the Company is not currently a party to any proceeding, the adverse outcome of which would have a material adverse effect on the Company s financial position or results of operations.

## Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders or otherwise for the three months ended December 31, 2007.

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#### **PART II**

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### **Market Information**

On August 21, 2007, Ciphergen Biosystems, Inc. changed its corporate name to Vermillion, Inc. s ( Vermillion ). In conjunction with the name change, Vermillion changed its common stock ticker symbol on the NASDAQ Capital Markets to VRML. Prior to the corporate name change, Vermillion s common stock was traded on the NASDAQ Capital Market under the symbols CIPH and CIPHE.

At the February 14, 2008, Special Meeting of Stockholders, the stockholders of Vermillion approved the proposal to authorize the Board of Directors in its discretion, without further authorization of Vermillion s stockholders, to amend Vermillion s Certificate of Incorporation to effect a reverse split of Vermillion s common stock by a ratio of between 1 for 6 to 1 for 10. On February 15, 2008, Vermillion s Board of Directors approved a 1 for 10 reverse stock split (the Reverse Stock Split ) of Vermillion s common stock effective at the close of business on Monday, March 3, 2008. Accordingly, all share and per share amounts were adjusted to reflect the impact of the Reverse Stock Split. On March 4, 2008, Vermillion s common stock began trading under the Reverse Stock Split basis. Additionally, beginning on March 4, 2008, Vermillion s common stock will trade for a period of 20 trading days under ticker symbol VRMLD as an interim symbol to denote its new status. After this 20 trading day period, Vermillion s common stock will resume trading under the ticker symbol VRML.

As of January 3, 2008, there were 142 holders of record of Vermillion s common stock, excluding shares held in book-entry form through The Depository Trust Company, and 3,937 beneficial owners of Vermillion s common stock. The closing price for Vermillion s common stock on February 29, 2008, was \$5.30.

The high and low sales prices of Vermillion s common stock as quoted on the NASDAQ Capital Market during the years ended December 31, 2007 and 2006, were as follows:

	20	2007		2006	
	High	Low	High	Low	
Three months ended March 31	\$ 19.90	\$ 9.20	\$ 22.50	\$ 10.00	
Three months ended June 30	15.30	8.50	18.60	10.00	
Three months ended September 30	11.50	5.50	17.30	8.50	
Three months ended December 31	10.90	5.80	13.90	8.20	

#### **Dividends**

Vermillion has never paid or declared any dividend on its common stock and does not anticipate paying cash dividends on its common stock in the foreseeable future. If Vermillion pays a cash dividend on its common stock, Vermillion 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 Vermillion s ability to declare and pay dividends on its common stock. Vermillion intends to retain all available funds and any future earnings to fund

the development and expansion of its business.

## **Unregistered Sales of Equity Securities**

On August 29, 2007, Vermillion completed a private placement sale of 2,451,309 shares of its common stock and warrants to purchase up to an additional 1,961,047 shares of its common stock with an exercise price of \$9.25 per share and expiration date of August 29, 2012, to a group of existing and new investors for \$20,591,000 in gross proceeds. The net proceeds of the transaction will be used for general working capital needs. In connection with Quest Diagnostics Incorporated s ( Quest ) participation in this transaction, Vermillion amended a warrant originally issued to Quest on July 22, 2005. Pursuant to the terms of the amendment, the warrant to purchase 220,000 shares of Vermillion s common stock was reduced from \$35.00 per share to \$25.00 per share and the

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expiration date was extended from July 22, 2010, to July 22, 2011. The sale, offer and issuance of the securities was exempt from registration under Section 4(2) and/or Rule 506 of Regulation D of the Securities Act, as a transaction not involving a public offering because, among other things, the investors were accredited investors at the time of the transaction and appropriate legends were affixed to the instruments representing such securities issued in such transaction.

As partial consideration for services as placement agent in connection with the August 29, 2007, private placement sale, Vermillion issued a warrant to Oppenheimer & Co. Inc. (Oppenheimer) to purchase up to 92,100 shares of Vermillion s common stock with an exercise price of \$9.25 per share and expiration date of August 29, 2012. Vermillion s Board of Directors determined the value of such warrants to be equal to the price paid for the warrants by the investors in the offering, or \$1.25 per warrant share, for an aggregate value of \$115,000. The sale, offer and issuance of the securities was exempt from registration under Section 4(2) and/or Rule 506 of Regulation D of the Securities Act, as a transaction not involving a public offering, because among other things, Oppenheimer was an accredited investor at the time of the transaction and appropriate legends were affixed to the instruments representing such securities issued in such transaction.

On November 15, 2006, Vermillion completed the sale of \$16,500,000 in aggregate principal of the 7.00% convertible senior notes due September 1, 2011 (the 7.00% Notes). The 7.00% Notes were sold pursuant to separate exchange and redemption agreements between Vermillion and certain holders of Vermillion's existing 4.50% convertible senior notes due September 1, 2008 (the 4.50% Notes). The holders agreed to exchange and redeem \$27,500,000 in aggregate principal of the 4.50% Notes for \$16,500,000 in aggregate principal of the 7.00% Notes and \$11,000,000 in cash, plus accrued and unpaid interest on the 4.50% Notes of \$254,000. Offering costs of \$104,000 and fees of \$514,500 were paid on behalf of the debt holders and recorded as a debt discount to the 7.00% Notes. The sale, offer and issuance of the securities was exempt from registration under Section 4(2) and/or Rule 506 of Regulation D of the Securities Act, as a transaction not involving a public offering, because among other things, the investors were accredited investors at the time of the transaction and appropriate legends were affixed to the instruments representing such securities issued in such transaction.

On August 3, 2006 and November 15, 2006, Vermillion issued warrants to purchase an aggregate of 20,000 shares of its common stock with an exercise price of \$12.60 per share to Oppenheimer in partial consideration for its services as the placement agent for the offering of the 7.00% Notes. Fees paid on behalf of the debt holders included the fair value of the two warrants were recorded as a discount on the 7.00% Notes. Fees paid on behalf of debt holders included the fair value of two warrants issued to Oppenheimer. Fees paid on behalf of debt holders included the fair value of the two warrants issued to Oppenheimer. The two warrants were valued at \$140,000 based on the fair value as determined by the Black Scholes method of valuation using a risk free interest rate of 4.75%, five year contractual life, and 88.00% volatility rate. The sale, offer and issuance of the securities was exempt from registration under Section 4(2) and/or Rule 506 of Regulation D of the Securities Act, as a transaction not involving a public offering, because among other things, Oppenheimer was an accredited investor at the time of the transaction and appropriate legends were affixed to the instruments representing such securities issued in such transaction.

In connection with the sale of assets and liabilities of its protein research products and collaborative services business to Bio-Rad Laboratories, Incorporated (Bio-Rad) on November 13, 2006, Vermillion sold to Bio-Rad 308,642 shares of Vermillion common stock for an aggregate purchase price of \$3,000,000. The sale, offer and issuance of the securities was exempt from registration under Section 4(2) and/or Rule 506 of Regulation D of the Securities Act, as a transaction not involving a public offering, because among other things, Bio-Rad was an accredited investor at the time of the transaction and appropriate legends were affixed to the instruments representing such securities issued in such transaction.

On July 22, 2005, Vermillion sold to Quest 622,500 shares of Vermillion common stock and issued a warrant to purchase up to 220,000 shares of Vermillion s common stock with an exercise price of \$35.00 per share, which was subsequently reduced to \$25.00 per share with the August 29, 2007, private placement sale, for \$14,954,000 in net proceeds. The sale, offer and issuance of the securities was exempt from registration under Section 4(2) and/or Rule 506 of Regulation D of the Securities Act, as a transaction not involving a public offering, because among

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other things, Quest was an accredited investor at the time of the transaction and appropriate legends were affixed to the instruments representing such securities issued in such transaction.

## **Securities Authorized for Issuance Under Equity Compensation Plans**

Vermillion currently maintains three equity-based compensation plans that were approved by its stockholders. The plans are the 1993 Stock Option Plan (the 1993 Plan ), the Amended and Restated 2000 Stock Plan (the 2000 Plan ) and the Amended and Restated 2000 Employee Stock Purchase Plan (the ESPP ).

1993 Plan. The authority Vermillion s Board of Directors to grant new stock options and awards under the 1993 Plan terminated in 2001. Vermillion s Board of Directors continues to administer the 1993 Plan with respect to the stock options that remain outstanding to Vermillion s officers, employees, directors and a consultant.

2000 Plan. Vermillion s Board of Directors or a committee of Vermillion s Board of Directors may grant stock options and stock awards under the 2000 Plan. Vermillion s officers, employees, directors and consultants are eligible to receive stock option grants and stock awards under the 2000 Plan. Vermillion s non-employee directors are also eligible for certain automatic stock option grants under the 2000 plan. Vermillion s Board of Directors administers the 2000 Plan and approves each stock option grant and stock award. Vermillion s Board of Directors or a committee of Vermillion s Board of Directors determines the per share purchase price of Vermillion s common stock related to stock option grants and stock awards under the 2000 Plan. Additionally, Vermillion s Board of Directors or a committee of Vermillion s Board of Directors determines the vesting schedule, duration, and other terms and conditions of each stock option grant or stock award subject to the limitations of the 2000 Plan.

ESPP. Subject to limits, all of Vermillion s officers and employees in the United States are eligible to participate in the ESPP. The ESPP operates in successive six-month offering and purchase periods. Participants in the ESPP may purchase common stock at the end of each purchase period at a purchase price equal to 85.0% of the lower of the fair market value of Vermillion s common stock at the beginning of the offering period or the end of the purchase period. The ESPP administrator may allow participants to contribute up to 15.0% of their eligible compensation to purchase stock under the ESPP. Vermillion s Board of Directors or a committee of Vermillion s Board of Directors administers the ESPP.

The number of shares of Vermillion 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, 2007, were as follows:

		Number of
		Securities
		Remaining
		Available for
		Future
		Issuance
Number of		Under
<b>Securities to</b>		
be	Weighted-	Equity
<b>Issued Upon</b>	Average	Compensation
-	Exercise	-
Exercise of	Price	Plans
Outstanding		(Excluding

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Plan Category	Options, Warrants and Rights	of Outstanding Options, Warrants and Rights		Shares Reflected in First Column)
Equity compensation plans approved by security holders Equity compensation plans not approved by security holders	472,461(1)	\$	26.19(2)	8,147,220(3)
Total	472,461	\$	26.19	8,147,220

<sup>(1)</sup> Includes outstanding stock options for 16,272 shares of Vermillion common stock under the 1993 Plan and 453,403 shares of Vermillion common stock under the 2000 Plan. Also includes 2,786 shares of Vermillion common stock after giving effect to estimated purchases under the ESPP for the purchase period that will end on May 1, 2008, based on participant contributions through December 31, 2007.

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- (2) Includes the weighted average stock price for outstanding stock options of \$31.19 under the 1993 Plan and \$26.13 for the 2000 Plan. Also includes the 2,786 shares of Vermillion common stock after giving effect to estimated purchases under the ESPP for the purchase period that will end on May 1, 2008, based on participant contributions through December 31, 2007, with an estimated per share price of \$6.89, which is calculated as 85% of the December 31, 2007, closing price of \$8.10.
- (3) Includes 6,776,983 shares of Vermillion common stock for the 2000 Plan. On January 1 of each year during the term of the 2000 Plan, the total number of shares available for award purposes under the 2000 Plan will increase by the lesser of (i) 215,000 shares, (ii) 5% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount determined by Vermillion s Board of Directors. Also includes 1,370,237 shares of Vermillion common stock for the ESPP after giving effect to estimated purchases of 2,786 shares of Vermillion common stock under the ESPP for the purchase period that will end on May 1, 2008, based on participant contributions through December 31, 2007. On January 1 of each year during the term of the ESPP, the total number of shares available for sale under the ESPP will increase by the lesser of (i) 43,000 shares, (ii) 1% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount determined by Vermillion s Board of Directors.

#### Item 6. Selected Financial Data

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

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## Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operation

You should read the following discussion in conjunction with Vermillion, Inc. (Vermillion), formerly Ciphergen Biosystems, Inc., and its wholly-owned subsidiaries (collectively the Company) audited consolidated financial statements and the accompanying notes in Part II Item 8, Financial Statements and Supplementary Data. The following discussion includes certain forward-looking statements that involve risks and uncertainties. Vermillion, Inc. and subsidiaries actual results could differ materially from those referred to in the forward-looking statements as a result of various factors, including those discussed in Part I Item 1A, Risk Factors, and elsewhere in this Annual Report on Form 10-K.

#### 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., Vermillion had its initial public offering on September 28, 2000. On November 13, 2006, the Company sold assets and liabilities of its protein research products and collaborative services business (the Instrument Business Sale ) to Bio-Rad Laboratories, Inc. (Bio-Rad ) in order to concentrate the Company s resources on developing clinical protein biomarker diagnostic products and services. On August 21, 2007, Ciphergen Biosystems, Inc. changed its corporate name to Vermillion, Inc. In conjunction with the name change, Vermillion changed its common stock ticker symbol on the NASDAQ Capital Markets from CIPH to VRML . Vermillion had a 1 for 10 reverse stock split of Vermillion s common stock effective at the close of business on March 3, 2008. Accordingly, all share and per share amounts were adjusted to reflect the impact of the 1 for 10 reverse stock split in this Annual Report on Form 10-K.

Prior to the Instrument Business Sale, the Company developed, manufactured and sold ProteinChip Systems for life science research. This patented technology is recognized as Surface Enhanced Laser Desorption/Ionization (SELDI). The systems consist of ProteinChip Readers, ProteinChip Software and related accessories, which were used in conjunction with consumable ProteinChip Arrays. These products were sold primarily to pharmaceutical companies, biotechnology companies, academic research laboratories and government research laboratories. The Company also provided research services through its Biomarker Discovery Center laboratories, and offered consulting services, customer support services and training classes to its customers and collaborators. The Company s sales were driven by the need for new and better tools to perform protein discovery, characterization, purification, identification and assay development. Many of the ProteinChip Systems sold to the Company s customers also generated revenue from the sale of consumables and maintenance contracts. In addition, some of the Company s customers would enhance their ProteinChip Systems by adding automation accessories and advanced software. The Company s expenses consisted primarily of materials, contracted manufacturing services, labor and overhead costs to manufacture its ProteinChip Systems and ProteinChip Arrays and to support customer services, marketing and sales activities, research and development programs, litigation and general and administrative costs associated with its operations.

Since the Instrument Business Sale, the Company has dedicated itself to the discovery, development and commercialization of novel diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Vermillion uses the process of utilizing advanced protein separation methods to identify and resolve variants of specific biomarkers (known as translational proteomics) for developing a procedure to measure a property or concentration of an analyte (known as an assay) and commercializing novel diagnostic tests. As a result of the transition from the Company s historical roots as a proteomics research products business to a novel diagnostic tests business, the Company has substantially reduced the size of its staff. Currently, the Company s expenses consist primarily of research and development costs related to its diagnostics efforts and general and administrative costs, including litigation expenses and accounting and auditing expenses.

Through collaborations with leading academic and research institutions, including 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, The Ohio State University Research Foundation and Stanford University, we plan to develop diagnostic tests in the fields of oncology, hematology, cardiology and women s health. Vermillion will also address clinical questions related to early disease

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detection, treatment response, monitoring of disease progression, prognosis and others. These research collaborations have provided Vermillion with the clinical data and intellectual property portfolio that form the basis of Vermillion s product pipeline. Vermillion is now engaged in product development and commercialization of discoveries made under these collaborations.

In July 2005, Vermillion entered into a strategic alliance agreement with Quest pursuant to which the parties have agreed to develop and commercialize up to three diagnostic tests. The term of the agreement ends on the later of (i) the three-year anniversary of the agreement and (ii) the date on which Quest commercializes the three diagnostic tests. Thus, Vermillion s major initiatives are currently aimed at commercializing these diagnostic tests, both within the context of its strategic alliance agreement with Quest as well as markets in which Quest does not participate, to the extent permitted under the strategic alliance agreement. In May 2007, Vermillion hired Steve Lundy, Senior Vice President of Sales and Marketing, to lead the commercialization effort of the Company.

We expect to incur losses for at least the next year. Due to the Instrument Business Sale, the Company will have limited revenues until its diagnostic tests are developed and successfully commercialized. To become profitable, the Company will need to complete development of key diagnostic tests, obtain FDA approval and successfully commercialize its products. The Company has a limited history of operations in developing diagnostic tests, and we anticipate that the Company s quarterly results of operations will fluctuate for the foreseeable future due to several factors, including market acceptance of current and new products, the timing and results of the Company s research and development efforts, the introduction of new products by the Company s competitors and possible patent or license issues. The Company s limited operating history as a diagnostics business makes accurate prediction of future results of operations difficult.

#### **Critical Accounting Policies and Estimates**

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

#### **Investments**

The appropriate classification of investments in marketable securities is determined at the time of purchase, and is reassessed at each balance sheet date. Auction rate securities, which settled in its most recent auction, with auction dates within one year or less of the previous auction date that have been identified for funding operations within one year or less are classified as available-for-sale short-term investments. Due to the recent disruptions in the credit markets and the uncertainty surrounding the Company s ability to the liquidate certain auction rate securities in the next twelve months if at all, auction rate securities that have failed to settle at auction subsequent to December 31, 2007, have been classified as available-for-sale long-term investments. Other marketable securities with maturities of one year or less from the date of purchase that have been identified for funding operations within one year or less are classified as available-for-sale short-term investments. All other marketable securities are classified as available-for-sale long-term investments.

These marketable securities are carried at fair value with unrealized gains or losses reported in accumulated other comprehensive loss. Fair value is generally based on quoted market price of the marketable security, and if the quoted market price is not available, the fair value is extrapolated from the quoted market prices of similar marketable securities or by discounting the future cash flows taking into consideration the interest rate probabilities that reflect the risk associated with that marketable security. Typically, the carrying value of auction rate securities approximates fair value due to the frequent resetting of the interest rates. Realized gains and losses on marketable securities are computed using the specific identification method and are reported in other income (expense), net. The amortized cost of marketable debt securities is adjusted for the amortization of premiums and accretion of

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discounts to maturity, which is included in interest income. Declines in value judged to be other-than-temporary is determined based on the specific identification method and are reported in other income (expense), net.

# Depreciation and Amortization

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. Machinery and equipment, demonstration equipment, computer equipment, computer software, development systems used for collaborations, and furniture and fixtures are depreciated using the straight-line method over the estimated useful life of the asset. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful lives of the improvement or the original term of the underlying lease. Repair and maintenance costs are expensed as incurred. Property, plant and equipment retired or otherwise disposed of and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is included in operating expenses. Property, plant and equipment are depreciated and amortized using the following estimated useful lives:

	Useful Life
Machinery and equipment	3 to 5 years
Demonstration equipment	2 years
Computer equipment	3 years
Computer software	3 years
Development systems used for collaborations	3 years
Furniture and fixtures	5 years
Leasehold improvements	2 to 8 years

**Estimated** 

Property, plant 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, plant and equipment are considered to be impaired, an impairment loss is recognized.

## **Stock-Based Compensation**

Prior to January 1, 2006, the Company accounted for employee stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board (the APB) Opinion No. 25, Accounting for Stock Issued to Employees, as allowed by Statement of Financial Accounting Standard (SFAS) No. 123 as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. Under the intrinsic value method, no stock-based employee compensation cost is recorded, provided the stock options are granted with an exercise price equal to or greater than the market value of the underlying common stock on the date of grant.

Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment*. Under SFAS No. 123(R), the total fair value of the stock options awards is expensed ratably over the service period of the employees receiving the awards. In adopting SFAS No. 123(R), the Company used the modified prospective method of adoption. Under this adoption method, compensation expense recognized subsequent to adoption includes: (a) compensation costs for all share-based awards granted prior to but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123 and (b) compensation costs for all share-based awards granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R).

In estimating the fair value of each stock option award on their respective grant dates and stock purchased under the 2000 Employee Stock Purchase Plan ( ESPP ), the Company uses the Black-Scholes pricing model. The Black-Scholes pricing model requires the Company to make assumptions with regard to the options granted and stock purchased under ESPP during a reporting period namely, expected life, stock price volatility, expected dividend yield and risk-free interest rate.

The expected life of options is based on historical data of Vermillion s actual experience with the options it has 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 the historical volatility of Vermillion s common stock for the year ended December 31,

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2007. The historical volatility covers a period that corresponds to the expected life of the options. For the year ended December 31, 2006, the Company used a combination of historical and peer group volatility for a blended volatility in deriving its expected volatility assumption as allowed under SFAS No. 123(R) and the SEC s Staff Accounting Bulletin (SAB) No. 107. At that point in time, the Company made an assessment that blended volatility is more representative of future stock price trends than just using historical or peer group volatility. The expected dividend yield is based on the estimated annual dividends that Vermillion expects to pay over the expected life of the options as a percentage of the market value of Vermillion s 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.

The expected life of shares purchased under ESPP is six months, which corresponds to the offering period. The expected stock price volatility is estimated using a six month historical volatility of Vermillion s common stock, which corresponds to the offering period. The expected dividend yield is based on the estimated annual dividends that Vermillion expects to pay over the expected life of shares purchased under ESPP as a percentage of the market value of Vermillion s common stock as of the grant date. The risk-free interest rate for the expected life of the shares purchased under ESPP is based on the United States Treasury yield curve in effect as of the beginning of the offering period.

The average assumptions used to calculate the fair value of options granted and shares purchasable under ESPP that were incorporated in the Black-Scholes pricing model for the years ended December 31, 2007 and 2006, were as follows:

	2000 Stock Plan		Employee Purchase	
	2007	2006	2007	2006
Dividend yield	%	%	%	%
Volatility	81.46%	86.23%	83.30%	84.55%
Risk-free interest rate	4.81%	4.80%	4.78%	4.96%
Expected lives (years)	5.20	6.07	0.50	0.50

#### **Contingencies**

The Company has been, and may in the future become, subject to legal proceedings related to intellectual property licensing matters. Based on the information available at the balance sheet dates and through consultation with the Company s legal counsel, we assess the likelihood of any adverse judgments or outcomes for these matters, as well as potential ranges of probable loss. If losses are probable and reasonably estimable, a reserve will be recorded in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies*. Currently, no such reserves have been recorded. Any reserves recorded in the future may change due to new developments in each matter.

# **Income Taxes**

On January 1, 2007, the Company adopted Financial Accounting Standards Board (the FASB) Interpretation No. (FIN) 48, *Accounting for Uncertainty in Income Taxes* an *Interpretation of FASB Statement No. 109*, which clarifies the accounting for income tax uncertainties that have been recognized in an enterprise s financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*. The results of the Internal Revenue Code 382 study conducted during the year ended December 31, 2007, led to a reduction of the Company s gross net operating loss deferred tax asset. As of December 31, 2007, the Company has not recorded any liability related to FIN 48. Since the

Company has incurred net losses since inception and all deferred tax assets have been fully reserved, FIN 48 had no impact to the Company s effective tax rate or retained earnings. Additionally, the Company has not recorded any interest or penalties related to FIN 48.

The provision for income taxes is based on income reported for financial statement purposes and differs from the amount of taxes currently payable, because certain income and expense items are reported for financial statement purposes in different periods than those for tax reporting purposes.

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The Company accounts 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 enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. Interest and penalties related to income taxes are recorded to interest and other expense of the consolidated statement of operations.

As part of the computation of the income tax provision, estimates and assumptions must be made regarding the deductibility of certain expenses and the treatment of tax contingencies. There is a possibility that these estimates and assumption may be disallowed as part of an audit by the various taxing authorities that the Company is subject to. Any differences between items taken as deductions in the Company s tax provision computations and those allowed by the taxing authorities could result in additional income tax expense in future periods.

# **Recent Accounting Pronouncements**

# Accounting for Business Combinations

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, which replaces SFAS No. 141, *Business Combinations*. SFAS No. 141(R) retains the fundamental requirements that the acquisition method of accounting, which was called the purchase method under SFAS No. 141, be used for all business combinations and for an acquirer to be identified for each business combination. SFAS No. 141(R) requires an acquirer to measure the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at their fair values at the acquisition date, with limited exceptions. This replaces the cost-allocation process under SFAS No. 141, which required the cost of an acquisition to be allocated to the individual assets acquired and liabilities assumed based on their estimated fair values. SFAS No. 141(R) also requires the acquirer in a business combination achieved in stages, which is sometimes referred to as a step acquisition, to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values or other amounts determined in accordance with SFAS No. 141(R). SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company is currently evaluating the impact from adopting SFAS No. 141(R) will have on its consolidated financial statements.

# Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities

In June 2007, the Emerging Issues Task Force (the EITF) reached a consensus on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. EITF Issue No. 07-3 requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF Issue No. 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company s adoption of EITF Issue No. 07-3 is not expected to have a material impact on its consolidated financial statements.

# Fair Value Option for Financial Assets and Financial Liabilities

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115.* SFAS No. 159 provides entities with an option to report selected financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair

value option has been elected are reported in earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company s adoption of SFAS No. 159 is not expected to have a material impact on its consolidated financial statements.

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#### Fair Value Measurements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years, with early adoption permitted. The Company s adoption of SFAS No. 157 is not expected to have a material impact on its consolidated financial statements.

# **Results of Operations**

# Year Ended December 31, 2007, Compared to Year Ended December 31, 2006

The selected summary financial and operating data of the Company for the years ended December 31, 2007 and 2006, were as follows (dollars in thousands):

		Ended aber 31, 2006	Increase (Decrease) Amount %			
Revenue:						
Products	\$	\$ 11,292	\$ (11,292)	(100.00)		
Services	44	6,923	(6,879)	(99.36)		
Total revenue	44	18,215	(18,171)	(99.76)		
Cost of revenue:						
Products		5,818	(5,818)	(100.00)		
Services	28	3,520	(3,492)	(99.20)		
Total cost of revenue	28	9,338	(9,310)	(99.70)		
Gross profit	16	8,877	(8,861)	(99.82)		
Operating expenses:						
Research and development	8,213	11,474	(3,261)	(28.42)		
Sales and marketing	2,175	12,568	(10,393)	(82.69)		
General and administrative	10,858	10,661	197	1.85		
Total operating expenses	21,246	34,703	(13,457)	(38.78)		
Gain on sale of Instrument Business	1,610	6,929	(5,319)	(76.76)		
Loss from operations	(19,620)	(18,897)	723	3.83		
Interest income	734	843	(109)	(12.93)		
Interest expense	(2,302)	(2,254)	48	2.13		

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Loss on extinguishment of debt Other income (expense), net	69	(1,481) (125)	(1,481) (194)	(100.00) (155.20)
Loss before income taxes	(21,119)	(21,914)	(795)	(3.63)
Income tax expense	(163)	(152)	11	7.24
Net loss	\$ (21,282)	\$ (22,066)	\$ (784)	(3.55)

*Products Revenue.* There was no products revenue for the year ended December 31, 2007, compared to \$11,292,000 for the same period in 2006. The decrease was the result of the Instrument Business Sale.

*Services Revenue.* Services revenue decreased to \$44,000 for the year ended December 31, 2007, from \$6,923,000 for the same period in 2006. Services revenue for the year ended December 31, 2007, was from ongoing support services provided to a customer. This decrease was the result of the Instrument Business Sale.

*Cost of Products Revenue.* There was no cost of products revenue for the year ended December 31, 2007, compared to \$5,818,000 for the same period in 2006. This decrease was the result of the Instrument Business Sale.

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*Cost of Services Revenue.* Cost of services revenue decreased to \$28,000 for the year ended December 31, 2007, from \$3,520,000 for the same period in 2006. Cost of services revenue for the year ended December 31, 2007, was from ongoing support services provided to a customer. This decrease was the result of the Instrument Business Sale.

Research and Development Expenses. Research and development expenses decreased by \$3,261,000, or 28.4%, to \$8,213,000 for the year ended December 31, 2007, from \$11,474,000 for the same period in 2006. This decrease is primarily due to the Company s transition from its historical roots as a proteomics research products business to a novel diagnostics test business following the Instrument Business Sale. Employee headcount decreased to fourteen at December 31, 2007, from nineteen just prior to the Instrument Business Sale, and, correspondingly, salaries, payroll taxes, employee benefits and stock-based compensation decreased by \$2,239,000; materials and supplies used in the development of new products decreased by \$190,000; equipment related expenses decreased by \$418,000; occupancy costs decreased by \$245,000; and other operating costs decreased by \$352,000. These decreases were offset by the increased collaboration cost spending of \$286,000. Stock-based compensation expense included in research and development expenses was \$167,000 and \$337,000 for the years ended December 31, 2007 and 2006, respectively.

Sales and Marketing Expenses. Sales and marketing expenses decreased by \$10,393,000, or 82.7%, to \$2,175,000 for the year ended December 31, 2007, from \$12,568,000 for the same period in 2006. The decrease was largely due to the Instrument Business Sale. Correspondingly, employee headcount decreased to five at December 31, 2007, from forty-five just prior to the Instrument Business Sale, which resulted in a decline in salaries, payroll taxes, employee benefits and stock-based compensation of \$6,329,000. This also resulted in reductions in travel by \$1,280,000; internal consumption of ProteinChip Arrays and other consumables for customer demonstrations and support by \$896,000; outside services by \$434,000; sales and marketing costs of \$430,000; and equipment related expenses by \$1,344,000. These decreases were offset by increased other operating expenses of \$550,000. Stock-based compensation expense included in sales and marketing expenses was \$88,000 and \$321,000 for the years ended December 31, 2007 and 2006, respectively.

General and Administrative Expenses. General and administrative expenses increased to \$10,858,000 for the year ended December 31, 2007, from \$10,661,000 for the same period in 2006, an increase of \$197,000 or 1.9%. The increase was primarily due to the settlement of the Health Discovery Corporation lawsuit of \$600,000; increased professional services of \$294,000 primarily from the Company s name change and printing costs associated with the annual proxy and annual financial report; increased domestic and international accounting and audit fees of \$383,000 due to the timing, additional work performed on the private management offering and additional work performed on the response to comment letters from the SEC. These increases were offset by decreases in equipment related expense of \$128,000; legal fees of \$203,000; and other operating expenses of \$362,000, primarily from the reduction in postage and shipping costs attributable to reduced activity resulting from the Instrument Business Sale. Additionally, salaries, payroll taxes, employee benefits and stock-based compensation decreased by \$505,000, which corresponds to the decrease in employee headcount to eleven at December 31, 2007, from fourteen just prior to the Instrument Business Sale. Stock-based compensation expense included in general and administrative expenses was \$623,000 and \$813,000 for the year ended December 31, 2007 and 2006, respectively.

Gain on Sale of Instrument Business. Gain on sale of the Instrument Business of \$1,610,000 for the year ended December 31, 2007, resulted from the receipt of \$2,000,000 from Bio-Rad related to the United States Patent and Trademark Office issuance of the reexamination certificate of the United States Patent No. 6,734,022 on October 23, 2007, offset by a \$390,000 post-closing adjustment related to the Instrument Business Sale. For the year ended December 31, 2006, the Company recognized a gain of \$6,929,000 from the Instrument Business Sale.

*Interest Income*. Interest income was \$734,000 for the year ended December 31, 2007, compared to \$843,000 for the same period in 2006. Interest income decreased primarily due to the lower interest rates and liquidation of interest bearing cash and cash equivalents during the year ended December 31, 2007, to fund operations.

*Interest Expense*. Interest expense was \$2,302,000 for the year ended December 31, 2007, compared to \$2,254,000 for the same period in 2006. Interest expense in both periods consisted largely of interest related to our convertible senior notes and borrowings from Quest. Interest expense included the amortization of the beneficial conversion feature associated with the 4.50% convertible senior notes due September 1, 2008, amounting to \$239,000 and \$488,000 for the years ended December 31, 2007 and 2006, respectively.

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Loss on Extinguishment of Debt. The loss from extinguishment of debt for the year ended December 31, 2006, represents the expensing of \$868,000 of unamortized debt discount and \$613,000 of unamortized prepaid offering costs related to the exchange of \$27,500,000 of the 4.50% convertible senior notes due September 1, 2008, for \$16,500,000 of 7.00% convertible senior notes and \$11,000,000 in cash.

Other Income/Expense, Net. Net other income was \$69,000 for the year ended December 31, 2007, compared to net other expense of \$125,000 for the same period in 2006. Net other income for the year ended December 31, 2007, included the net realized foreign currency exchange gain of \$109,000 due to the Company s reduction in foreign operations and foreign subsidiary balances, and increase in foreign currency exchange rates, and was offset by the offering costs amortization related to the convertible senior notes of \$71,000. Net other expense for the year ended December 31, 2006, included the net realized foreign currency exchange loss of \$21,000 and offering costs amortization related to the convertible senior notes of \$332,000, and was offset by the \$160,000 received in settlement of a claim against a service provider.

*Income Tax Expense.* Income taxes for the year ended December 31, 2007, was an expense of \$163,000 compared to an expense of \$152,000 for the same period in 2006. Income tax expense was due to foreign income taxes.

The Company has incurred net losses since inception and consequently is not subject to corporate income taxes in the United States to the extent of its tax loss carryforwards. At December 31, 2007, the Company had net operating loss carryforwards of \$40,332,000 for federal and \$43,730,000 for state tax purposes. If not utilized, these carryforwards will begin to expire in 2009 for federal purposes and 2008 for state purposes. As of December 31, 2007, we had \$2,609,000 of net operation carryforwards from our Japan operations. If not utilized, this carryforward will begin to expire in 2012. We also have research credit carryforwards of \$109,000 and \$4,918,000 million for federal and state tax purposes, respectively. If not utilized, the federal research credit carryforwards will expire in various amounts beginning in 2017. The California research credit can be carried forward indefinitely. The utilization of net operating loss carryforwards to reduce future income taxes will depend on the Company s ability to generate sufficient taxable income prior to the expiration of the net operating loss carryforwards. In addition, the maximum annual use of the net operating loss carryforwards may be limited in situations where changes occur in the Company s stock ownership.

The Company has incurred income tax liabilities primarily in France and Japan, as well as in most of the other countries outside the United States in which it operates. The Company has used net operating loss carryforwards to reduce its income tax liabilities in Japan and the United Kingdom. The net loss for the years ended December 31, 2007 and 2006, can be carried forward for seven years.

# **Liquidity and Capital Resources**

From the Company s inception through December 31, 2007, the Company has financed its operations principally with \$229,300,000 from the sales of products and services to customers and \$182,776,000 of net proceeds from debt and equity financings. This includes net proceeds of \$92,435,000 from Vermillion s initial public offering on September 28, 2000; net proceeds of \$26,902,000 from Vermillion s Series E Preferred Stock financing in March 2000; net proceeds of \$14,954,000 from the sale of 622,500 shares of Vermillion common stock and a warrant to purchase 220,000 shares of Vermillion common stock to Quest on July 22, 2005; net proceeds of \$3,000,000 from the sale of 308,642 shares of Vermillion common stock to Bio-Rad in connection with the Instrument Business Sale on November 13, 2006; and net proceeds of \$18,927,000 from the sale of 2,451,309 shares of Vermillion common stock and warrants for 1,961,047 shares of Vermillion common stock to a group of new and existing investors on August 29, 2007. Additionally, in connection with the strategic alliance agreement dated July 22, 2005, with Quest, Vermillion has drawn \$10,000,000 from this secured line of credit as of December 31, 2007, solely to fund certain development activities related to its strategic alliance. The Company also received net proceeds of \$15,218,000 from the Instrument Business Sale to Bio-Rad on November 13, 2006, and an additional \$2,000,000 withheld by Bio-Rad

related to the United States Patent and Trademark Office issuance of the reexamination certificate of the United States Patent No. 6,734,022 on October 23, 2007. The Company received net proceeds of \$27,011,000 from the sale of its BioSepra business on November 24, 2004, and an additional \$1,021,000, including interest, held in an interest-bearing escrow account for one year after the sale on December 1, 2005.

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Cash Flow from Investing Activities Correction. During the year-end close process, the Company became aware that it had incorrectly classified \$2,500,000 of short-term investments as cash and cash equivalents on its balance sheet as of June 30, 2007, as filed in the Company s Quarterly Report on Form 10Q for the quarterly period ended June 30, 2007. The misclassification resulted in understating short-term investments and overstating cash and cash equivalents by \$2,500,000 on the balance sheet and understating cash used in investing activities and changes in cash and cash equivalents by \$2,500,000 on the statement of cash flows for the six months ended June 30, 2007. The classification error had no effect on net loss or net cash used in operating activities or net cash provided by financing activities for the period. Short-term investments were properly classified on the balance sheet in the Company s filings for subsequent periods. The statement of cash flow for the six months ended June 30, 2007, will be corrected when the Company files its Quarterly Report on Form 10Q for the quarterly period ending June 30, 2008.

Cash and cash equivalents at December 31, 2007 and 2006, were \$7,617,000 and \$17,711,000, respectively. Working capital at December 31, 2007 and 2006, was \$8,534,000 and \$12,994,000, respectively. The decrease in working capital for the year ended December 31, 2007, was principally due to funds used to finance operating losses of \$21,282,000, offset by the net proceeds of \$18,927,000 from the sale 2,451,309 shares of Vermillion common stock and warrants to purchase 1,961,047 shares of Vermillion common stock to a group of investors.

Net cash used in operating activities was \$20,268,000 for the year ended December 31, 2007, primarily as a result of the \$21,282,000 net loss reduced by \$707,000 of noncash expenses that included the gain on the Instrument Business Sale of \$1,610,000, and offset by depreciation and amortization of \$1,181,000, stock-based compensation of \$878,000 and amortization of convertible senior notes discount of \$239,000. Net cash used in operating activities was also decreased by \$307,000 of cash provided by changes in operating assets and liabilities.

Net cash used in investing activities was \$11,684,000 for the year ended December 31, 2007, which primarily resulted from the net purchases of investments available-for-sale of \$12,875,000 and the acquisition of robotics machinery and other equipment for laboratory use and service of collaboration partner instruments of \$864,000, offset by the receipt of \$2,000,000 from Bio-Rad related to the United States Patent and Trademark Office issuance of the reexamination certificate of the United States Patent No. 6,734,022 on October 23, 2007.

Additionally, at December 31, 2007, the Company s investments consisted of \$12,777,000 invested in auction rate securities, including \$3,902,000 classified as available-for-sale long-term investments as a result of certain auction rate securities failing to settle at auctions subsequent to December 31, 2007. These auction rate securities have a rating of AAA by a major credit rating agency. As of March 24, 2008, the Company s entire investment portfolio of \$6,500,000 was invested in auction rate securities, which failed to settle at auctions from January 1, 2008, to March 24, 2008, due to the current overall credit concerns in the capital markets, and are classified as available-for-sale long-term investments. The investment portfolio at March 24, 2008, consists of \$3,902,000 of auction rate securities classified as available-for-sale long-term investments at December 31, 2007, and an additional \$2,500,000 of auction rate securities purchased during January and February 2008, which failed to settle at auctions during March 2008. These auction rate securities provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, which is generally every 28 days. The failure of the auctions impact the Company s ability to readily liquidate its auction rate securities into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument. The Company continues to earn interest on the investments that failed to settle at auction, at the maximum contractual rate. The Company will continue to monitor the value of its auction rate securities each reporting period for a possible impairment if a decline in fair value occurs.

Net cash provided by financing activities was \$21,910,000 for the year ended December 31, 2007, which primarily resulted from the net proceeds of \$18,927,000 from the sale of 2,451,309 shares of Vermillion common stock and warrants to purchase 1,961,047 shares of Vermillion common stock to a group of investors and the receipt of

\$2,917,000 in proceeds from the secured line of credit with Quest.

Net cash used in operating activities was \$20,439,000 for the year ended December 31, 2006, primarily as a result of the \$22,066,000 net loss reduced by \$1,295,000 of noncash expenses that included the gain on the Instrument Business Sale of \$6,929,000, and offset by the loss on extinguishment of the 4.50% convertible senior

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notes of \$1,481,000, depreciation and amortization of \$4,082,000, stock-based compensation of \$1,615,000 and amortization of convertible senior notes discount of \$488,000. Net cash used in operating activities was also decreased by \$332,000 of cash provided by changes in operating assets and liabilities.

Net cash provided by investing activities was \$16,528,000 for the year ended December 31, 2006, which primarily resulted from proceeds received from the Instrument Business Sale of \$15,218,000 and the sale of an investment available-for-sale of \$2,245,000.

Net cash used in financing activities was \$4,168,000 for the year ended December 31, 2006, which primarily resulted from the principal payment of the 4.50% convertible senior notes of \$11,000,000, and was offset by the net proceeds of \$3,000,000 from the sale of 308,642 shares of Vermillion common stock to Bio-Rad in connection with the Instrument Business Sale and the receipt of \$4,583,000 in proceeds from the secured line of credit with Quest.

The Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2007, the Company had an accumulated deficit of \$239,142,000. On November 13, 2006, the Company completed the Instrument Business Sale to Bio-Rad, and as a result the Company currently concentrates its resources on developing clinical protein biomarker diagnostic products and services, and it does not have a source of revenue. Management believes that current available resources will not be sufficient to fund the Company s obligations. The Company s ability to continue to meet its obligations and to achieve its business objectives is dependent upon, among other things, raising additional capital or generating sufficient revenue in excess of costs. At such time as the Company requires additional funding, the Company may seek to raise such additional funding from various possible sources, including the public equity market, private financings, sales of assets, collaborative arrangements and debt. If additional capital is raised through the issuance of equity securities or securities convertible into equity, stockholders will experience dilution, and such securities may have rights, preferences or privileges senior to those of the holders of common stock or convertible senior notes. If the Company obtains additional funds through arrangements with collaborators or strategic partners, the Company may be required to relinquish its rights to certain technologies or products that it might otherwise seek to retain. There can be no assurance that the Company will be able to obtain such financing, or obtain it on acceptable terms. If the Company is unable to obtain financing on acceptable terms, it may be unable to execute its business plan, the Company could be required to delay or reduce the scope of its operations, and the Company may not be able to pay off the convertible senior notes if and when they come due.

The Company s inability to operate profitably and to consistently generate cash flows from operations and its reliance on external funding either from loans or equity, raise substantial doubt about the Company s ability to continue as a going concern.

#### **Off Balance Sheet Arrangements**

As of December 31, 2007, 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

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

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# Item 8. Financial Statements and Supplementary Data

# Vermillion, Inc. and Subsidiaries

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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 index appearing under Item 15(a)(1), present fairly, in all material respects, the financial position of Vermillion, Inc. and its subsidiaries at December 31, 2007 and 2006, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and negative cash flows from operations and has a net capital deficiency that 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/ PricewaterhouseCoopers LLP

San Jose, California March 31, 2008

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# Vermillion, Inc. and Subsidiaries

# Consolidated Balance Sheets (Dollars in thousands, except share and par value amounts)

		<b>Decem 2007</b>	ber 3	1, 2006
ASSETS				
Current assets:				
Cash and cash equivalents	\$	7,617	\$	17,711
Short-term investments, at fair value Accounts receivable, net of allowance for doubtful accounts of \$- and \$2 at		8,875		
December 31, 2007 and 2006, respectively		19		29
Prepaid expenses and other current assets		1,064		2,300
•		•		•
Total current assets		17,575		20,040
Property, plant and equipment, net		1,938		2,260
Long-term investments, at fair value		3,902		716
Other assets		638		716
Total assets	\$	24,053	\$	23,016
LIABILITIES AND STOCKHOLDERS DEFICI	Г			
Current liabilities:	-			
Accounts payable	\$	2,975	\$	2,401
Accrued liabilities		3,595		4,645
Current portion of convertible senior notes, net of discounts		2,471		
Total current liabilities		9,041		7,046
Long-term debt owed to related party		10,000		7,083
Convertible senior notes, net of discount		16,196		18,428
Other liabilities		278		360
Total liabilities		35,515		32,917
Commitments and contingencies (Note 11)				
Stockholders deficit:				
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and				
outstanding at December 31, 2007 and 2006				
Common stock, \$0.001 par value, 150,000,000 and 80,000,000 shares authorized at December 31, 2007 and 2006, respectively; 6,380,197 and 3,922,044 shares issued				
and outstanding at December 31, 2007 and 2006, respectively		6		39
Additional paid-in capital		227,895		207,991
Accumulated deficit		(239,142)		(217,860)

Accumulated other comprehensive loss (221) (71)

Total stockholders deficit (11,462) (9,901)

Total liabilities and stockholders deficit \$24,053 \$23,016

See accompanying notes to consolidated financial statements.

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# Vermillion, Inc. and Subsidiaries

# Consolidated Statements of Operations (Dollars in thousands, except share and per share amounts)

	Year Ended I 2007			December 31, 2006			
Revenue: Products	\$		\$	11,292			
Services		44		6,923			
Total revenue		44		18,215			
Cost of revenue:				<b>~</b> 0.40			
Products		20		5,818			
Services		28		3,520			
Total cost of revenue		28		9,338			
Gross profit		16		8,877			
Operating expenses:							
Research and development		8,213		11,474			
Sales and marketing		2,175		12,568			
General and administrative		10,858		10,661			
Total operating expenses		21,246		34,703			
Gain on sale of instrument business		1,610		6,929			
Loss from operations		(19,620)		(18,897)			
Interest income		734		843			
Interest expense		(2,302)		(2,254)			
Loss on extinguishment of debt				(1,481)			
Other income (expense), net		69		(125)			
Loss before income taxes		(21,119)		(21,914)			
Income tax expense		(163)		(152)			
Net loss	\$	(21,282)	\$	(22,066)			
Loss per share basic and diluted	\$	(4.47)	\$	(6.05)			
Shares used to compute basic and diluted loss per common share		4,765,341		3,646,473			

See accompanying notes to consolidated financial statements.

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# Vermillion, Inc. and Subsidiaries

# Consolidated Statements of Changes in Stockholders Equity (Deficit) and Comprehensive Loss (Dollars in thousands, except share and per share amounts)

	Common Stock			Additional Paid-in									
	Shares	Am	ount		Capital		Deficit	]	Loss		Deficit)		Loss
Balance at December 31, 2005 Net loss Foreign currency translation adjustment	3,599,888	\$	36	\$	202,485	\$	(195,794) (22,066)	\$	(204)	\$	6,523 (22,066) 133	\$	(22,066)
Comprehensive loss												\$	(21,933)
Common stock shares issued in connection with: Exercise of stock													
options Employee stock	2,485				12						12		
purchase plan Private offering to Bio-Rad Laboratories,	11,029				131						131		
Inc. Value assigned to warrants issued to Oppenheimer & Co.,	308,642		3		3,608						3,611		
Inc.					140						140		
Stock compensation charge					1,615						1,615		
Balance at December 31, 2006 Net loss Unrealized loss on	3,922,044	\$	39	\$	207,991	\$	(217,860) (21,282)	\$	(71)	\$	(9,901) (21,282)	\$	(21,282)
available for sale securities Foreign currency									(98)		(98)		(98)
translation adjustment									(52)		(52)		(52)

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Comprehensive loss						\$ (21,432)
Common stock shares issued in connection with:  Exercise of stock						
options Employee stock	2,031		24		24	
purchase plan Private placement offering, net of issuance costs and	4,813		42		42	
registration fees Effect of 1 for 10	2,451,309	25	18,902		18,927	
reverse stock split Stock compensation		(58)	58			
charge			878		878	
Balance at December 31, 2007	6,380,197	\$ 6	\$ 227,895	\$ (239,142) \$	(221) \$ (11,462)	

See accompanying notes to consolidated financial statements.

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# Vermillion, Inc. and Subsidiaries

# Consolidated Statements of Cash Flows (Dollars in thousands)

	Year I Decem	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (21,282)	\$ (22,066)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of instrument business	(1,610)	(6,929)
Loss on extinguishment of convertible senior notes		1,481
Depreciation and amortization	1,181	4,082
Stock-based compensation expense	878	1,615
Amortization of debt discount associated with beneficial conversion feature of		
convertible senior notes	239	488
Amortization of debt issuance costs	71	332
(Gain) loss on sale and retirement of fixed assets	(50)	35
Provision for (recovery of) bad debt	(2)	66
Loss on write-down of inventory		130
Accrued investment income		(5)
Changes in operating assets and liabilities:		
Decrease in accounts receivable	12	3,207
Decrease (increase) in prepaid expenses and other current assets	877	(647)
Decrease in inventories		136
Decrease in other assets	19	145
Decrease in accounts payable and accrued liabilities	(501)	(1,075)
Decrease in deferred revenue	(18)	(1,174)
Decrease in other liabilities	(82)	(260)
Net cash used in operating activities	(20,268)	(20,439)
Cash flows from investing activities:		
Sales of investments	6,300	2,245
Purchases of investments	(19,175)	
Proceeds from sale of instrument business	2,000	15,218
Proceeds from sale of property, plant and equipment	55	
Purchase of property, plant and equipment	(864)	(589)
Payment for license related to litigation settlement		(346)
Net cash provided by (used in) investing activities	(11,684)	16,528
Cash flows from financing activities:		
	18,927	

Proceeds from private placement offering of common stock and common stock warrants, net of issuance costs and registration fees Proceeds from issuance of common stock to Bio-Rad Laboratories, Inc. 3.000 Proceeds from exercises of stock options 24 12 Proceeds from purchase of common stock by employee stock purchase plan 42 130 Proceeds from secured line of credit with Quest Diagnostics Incorporated 2,917 4,583 Principal payments on capital lease obligations (37)Principal payments on equipment financing loan (377)Debt discount and issuance costs on convertible senior notes (479)Principal payment on convertible senior notes (11,000)Net cash provided by (used in) financing activities 21,910 (4,168)52 Effect of exchange rate changes on cash and cash equivalents (52)Net increase (decrease) in cash and cash equivalents (10,094)(8,027)Cash and cash equivalents, beginning of period 17,711 25,738 7,617 Cash and cash equivalents, end of period \$ 17,711

See accompanying notes to consolidated financial statements

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## Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements**

## 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 the Company ), formerly Ciphergen Biosystems, Inc., is incorporated in the state of Delaware, and is engaged in the business of discovering, developing and commercializing diagnostics tests in the fields of oncology, hematology, cardiology and women s health.

Prior to the November 13, 2006, sale of assets and liabilities of the Company s protein research tools and collaborative services business (the Instrument Business Sale ) to Bio-Rad Laboratories, Inc. (Bio-Rad), the Company developed, manufactured and sold ProteinChip Systems for life sciences research. This patented technology is recognized as Surface Enhanced Laser Desorption/Ionization (SELDI). The systems consist of ProteinChip Readers, ProteinChip Software and related accessories, which were used in conjunction with consumable ProteinChip Arrays. These products were sold primarily to biologists at pharmaceutical and biotechnology companies, and academic and government research laboratories. The Company also provided research services through its Biomarker Discovery Center laboratories, and offered consulting services, customer support services and training classes to its customers and collaborators.

The accompanying consolidated financial statements of the Company were prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant net losses and negative cash flows from operations since inception. At December 31, 2007, the Company had an accumulated deficit of \$239,142,000. On November 13, 2006, the Company completed the Instrument Business Sale to Bio-Rad, and as a result the Company currently concentrates its resources on developing clinical protein biomarker diagnostic products and services, and it does not have a source of revenue. Management believes that current available resources will not be sufficient to fund the Company s obligations. The Company s ability to continue to meet its obligations and to achieve its business objectives is dependent upon, among other things, raising additional capital or generating sufficient revenue in excess of costs. At such time as the Company requires additional funding, the Company may seek to raise such additional funding from various possible sources, including the public equity market, private financings, sales of assets, collaborative arrangements and debt. If additional capital is raised through the issuance of equity securities or securities convertible into equity, stockholders will experience dilution, and such securities may have rights, preferences or privileges senior to those of the holders of common stock or convertible senior notes. If the Company obtains additional funds through arrangements with collaborators or strategic partners, the Company may be required to relinquish its rights to certain technologies or products that it might otherwise seek to retain. There can be no assurance that the Company will be able to obtain such financing, or obtain it on acceptable terms. If the Company is unable to obtain financing on acceptable terms, it may be unable to execute its business plan, the Company could be required to delay or reduce the scope of its operations, and it may not be able to pay off the convertible senior notes if and when they come due.

The Company s inability to operate profitably and to consistently generate cash flows from operations and its reliance on external funding either from loans or equity, raise substantial doubt about the Company s ability to continue as a going concern.

# Principals of Consolidation

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

# **Basis of Presentation**

At the February 14, 2008, Special Meeting of Stockholders, the stockholders of Vermillion approved the proposal to authorize the Board of Directors in its discretion, without further authorization of Vermillion s stockholders, to amend Vermillion s Certificate of Incorporation to effect a reverse split of Vermillion s common stock by a ratio of between 1 for 6 to 1 for 10. On February 15, 2008, Vermillion s Board of Directors approved a

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## Vermillion, Inc. and Subsidiaries

## **Notes to Consolidated Financial Statements** (Continued)

1 for 10 reverse stock split (the Reverse Stock Split ) of Vermillion s common stock effective at the close of business on Monday, March 3, 2008. Accordingly, basic and diluted loss per share on the consolidated statement of operations for the year ended December 31, 2007 and 2006, was adjusted to reflect the impact of the Reverse Stock Split. The number of issued and outstanding shares of Vermillion s common stock on the consolidated balance sheets at December 31, 2007 and 2006, consolidated statement of changes in stockholders equity (deficit) and comprehensive loss at and for the years ended December 31, 2007 and 2006, was also adjusted to take into account the Reverse Stock Split. Additionally, all share and per share amounts were adjusted to take into account the Reverse Stock Split in the accompanying notes to the consolidated financial statements.

# Use of Estimates

The preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. 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.

## **Investments**

The appropriate classification of investments in marketable securities is determined at the time of purchase, and is reassessed at each balance sheet date. Auction rate securities, which settled in its most recent auction, with auction dates within one year or less of the previous auction date that have been identified for funding operations within one year or less are classified as available-for-sale short-term investments. Due to the recent disruptions in the credit markets and the uncertainty surrounding the Company s ability to the liquidate certain auction rate securities in the next twelve months if at all auction rate securities that have failed to settle at auction subsequent to December 31, 2007, have been classified as available-for-sale long-term investments. Other marketable securities with maturities of one year or less from the date of purchase and have been identified for funding operations within one year or less are classified as available-for-sale short-term investments. All other marketable securities are classified as available-for-sale long-term investments.

These marketable securities are carried at fair value with unrealized gains or losses reported in accumulated other comprehensive loss. Fair value is generally based on quoted market price of the marketable security, and if the quoted market price is not available, the fair value is extrapolated from the quoted market prices of similar marketable securities or by discounting the future cash flows taking into consideration the interest rate probabilities that reflect the risk associated with that marketable security. Typically, the carrying value of auction rate securities approximates fair value due to the frequent resetting of the interest rates. Realized gains and losses on marketable securities are

computed using the specific identification method and are reported in other income (expense), net. The amortized cost of marketable debt securities is adjusted for the amortization of premiums and accretion of discounts to maturity, which is included in interest income. Declines in value judged to be other-than-temporary is determined based on the specific identification method and are reported in other income (expense), net.

# Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, investments in marketable securities and accounts receivable. The Company maintains the majority of its cash and cash equivalents in recognized financial institutions in the United States. The Company also

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#### Vermillion, Inc. and Subsidiaries

## **Notes to Consolidated Financial Statements** (Continued)

maintains cash deposits with banks in Western Europe, Canada, China and Japan. The Company has not experienced any losses associated with its deposits of cash and cash equivalents. The Company s investment in marketable securities consists of auction rate securities, and are managed by recognized financial institutions. The Company does not invest in derivative instruments or engage in hedging activities.

The Company s accounts receivable are derived from sales made to customers located in North America. The Company performs ongoing credit evaluations of its customers financial condition and generally does not require collateral. The Company maintains an allowance for doubtful accounts based upon the expected collectability of accounts receivable. The Company s accounts receivable at December 31, 2007, and revenues for the year ended at December 31, 2007, is from one customer. No customer accounted for more than 10.0% of revenue for the year ended December 31, 2006.

# **Inventory**

Inventory is stated at the lower of standard cost, which approximates cost on a first-in, first-out basis, or market value. Cost includes direct materials, direct labor, contracted manufacturing services and manufacturing overhead. Reserves for potentially excess and obsolete inventory are recorded based on management s analysis of inventory levels, planned changes in product offerings, sales forecasts and other factors.

# Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. Machinery and equipment, demonstration equipment, computer equipment, computer software, development systems used for collaborations, and furniture and fixtures are depreciated using the straight-line method over the estimated useful life of the asset. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful lives of the improvement or the original term of the underlying lease. Repair and maintenance costs are expensed as incurred. Property, plant and equipment retired or otherwise disposed of and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is included in operating expenses. Property, plant and equipment are depreciated and amortized using the following estimated useful lives:

	Useful Life
Machinery and equipment	3 to 5 years
Demonstration equipment	2 years
Computer equipment	3 years
Computer software	3 years
Development systems used for collaborations	3 years
Furniture and fixtures	5 years
Leasehold improvements	2 to 8 years

**Estimated** 

Property, plant 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, plant and equipment are considered to be impaired,

an impairment loss is recognized.

# Goodwill and Other Intangible Assets

Goodwill represents the purchase price amount paid over the fair value of the net assets of an acquired business. Goodwill is tested annually for impairment or more frequently if conditions arise that might indicate the carrying amount of goodwill may be impaired. Impairment of goodwill is determined by comparing the estimated fair value to the net book value of the reporting unit. The estimated fair value of the reporting unit is calculated using the discounted future cash flow method. If the net book value of a reporting unit exceeds its estimated fair value, the amount of the impairment loss is measured by comparing the reporting unit s implied goodwill estimated fair value to its carrying amount of that goodwill. To the extent that the carrying amount of a reporting unit s goodwill exceeds its implied fair value, a goodwill impairment loss is recognized.

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## Vermillion, Inc. and Subsidiaries

# **Notes to Consolidated Financial Statements** (Continued)

Other intangible assets represented a technology license acquired in connection with the settlement of litigation in 2003, which is stated at cost and was being amortized on a straight-line basis over its estimated useful life of 17 years. Other intangible assets were reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may no longer be recoverable.

# Revenue Recognition

Prior to the Instrument Business Sale, revenue from product sales, including systems, accessories and consumables was recognized upon product shipment, provided no significant obligations remain and collection of the receivables was reasonably assured. Revenue from shipping and handling was generally recognized upon product shipment, based on the amount billed to customers for shipping and handling. The related cost of shipping and handling was included in cost of revenue upon product shipment.

Revenue from sales of separately priced software products was recognized when realized or realizable and earned after meeting the following criteria:

persuasive evidence of an agreement existed;

the price was fixed or determinable;

the product was delivered;

no significant obligations remained; and

collection of the receivable was deemed probable.

The Company generally included a standard 12-month warranty on its instruments and accessories in the form of a maintenance contract upon initial sale. The Company also sold separately priced maintenance (extended warranty) contracts, which were generally for 12 or 24 months, upon expiration of the initial maintenance contract. Coverage under both the standard and extended maintenance contracts was identical. Revenue for both the standard and extended maintenance contracts was deferred and recognized ratably over the maintenance contract term. Related costs were expensed as incurred. Factors that affected the Company s warranty costs included the number of installed units, historical and anticipated rates of warranty claims, and cost per claim.

For revenue arrangements with multiple elements that are delivered at different points in time (for example, where Vermillion delivered the hardware and software but was also obligated to provide services, maintenance and/or training), the Company evaluated whether the delivered elements had standalone value to the customer, whether the fair value of the undelivered elements was reliably determinable, and whether the delivery of the remaining elements was probable and within the Company s control. When all these conditions were met, the Company recognized revenue on the delivered elements. If any one of these conditions were not met, the Company deferred the recognition of revenue until all these conditions were met or all elements had been delivered. Fair values for ongoing maintenance were based upon separate sales of renewals to other customers. Fair values for services, such as training or consulting, were based upon separate sales by the Company of those services to other customers.

# 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. Software development costs incurred in the research and development of new products are expensed as incurred until technological feasibility is established. To date, products and upgrades have generally reached technological feasibility and have been released for sale at substantially the same time.

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## Vermillion, Inc. and Subsidiaries

# Notes to Consolidated Financial Statements (Continued)

## **Stock-Based Compensation**

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment. Under SFAS No. 123(R), the total fair value of the stock options awards is expensed ratably over the service period of the employees receiving the awards. In adopting SFAS No. 123(R), the Company used the modified prospective method of adoption. Under this adoption method, compensation expense recognized subsequent to adoption includes: (a) compensation costs for all share-based awards granted prior to but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, Accounting for Stock-Based Compensation, and (b) compensation costs for all share-based awards granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R).

Prior to January 1, 2006, the Company accounted for employee stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board (the APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, as allowed by SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. Under the intrinsic value method, no stock-based employee compensation cost is recorded, provided the stock options are granted with an exercise price equal to or greater than the market value of the underlying common stock on the date of grant. Unearned compensation expense was based on the difference, if any, on the date of the grant between the fair value of the Company s stock and the exercise price. Unearned compensation was amortized and expensed using an accelerated method. The Company accounted for stock issued to non-employees using the fair value method of accounting as prescribed under Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. As of December 31, 2007, the Company had three stock-based employee compensation plans (see description of the three stock-based compensation plans in Note 15, Employee Benefit Plans).

#### **Income Taxes**

The Company accounts 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 expected to be realized. Interest and penalties related to income taxes are recorded to interest and other expense of the consolidated statement of operations.

On January 1, 2007, the Company adopted FASB Interpretation No. (FIN) 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*, which clarifies the accounting for income tax uncertainties that have been recognized in an enterprise s financial statements in accordance with Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes*. The results of the Internal Revenue Code 382 study conducted during the year ended December 31, 2007, led to a reduction of the Company s gross net operating loss deferred tax asset. As of December 31, 2007, the Company has not recorded any liability related to FIN 48. Since the Company has incurred net losses since inception and all deferred tax assets have been fully reserved, FIN 48 had no impact to the Company s effective tax rate or retained earnings. Additionally, the Company has not recorded any interest or penalties related to FIN 48.

# Foreign Currency Translation

The functional currency of Ciphergen Biosystems KK 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 revenues and 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.

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## Vermillion, Inc. and Subsidiaries

# **Notes to Consolidated Financial Statements** (Continued)

The functional currency of all other foreign operations is the United States dollar. Accordingly, all monetary assets and liabilities of these foreign operations are translated into United States dollars at current period-end exchange rates and non-monetary assets and related elements of expense are translated using historical rates of exchange. Income and expense elements are translated to United States dollars using average exchange rates in effect during the period. Gains and losses from the foreign currency transactions of these subsidiaries are recorded as other income (expense), net and were not material for the years ended December 31, 2007 and 2006.

# Accumulated Other Comprehensive Loss

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

#### Loss Per Share

Basic loss per share is computed by dividing the net loss by the weighted average number of common stock shares outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of common stock shares adjusted for the dilutive effect of common stock equivalent shares outstanding during the period. Common stock equivalents consist of convertible senior notes (using the as if converted method), stock options, stock warrants and common stock issuable under the 2000 Employee Stock Purchase Plan (using the treasury stock method). Common equivalent shares are excluded from the computation in periods in which they have an anti-dilutive effect on earnings per share.

# Fair Value of Financial Instruments

Financial instruments include cash and cash equivalents, marketable securities, accounts receivables, accounts payable, accrued liabilities, convertible senior notes and the amount owed on a secured line of credit with Quest Diagnostics Incorporated ( Quest ). The estimated fair value of financial instruments has been determined using available market information or other appropriate valuation methodologies. However, considerable judgment is required in interpreting market data to develop estimates of fair value; therefore, the estimates are not necessarily indicative of the amounts that could be realized or would be paid in a current market exchange. The effect of using different market assumptions and/or estimation methodologies may be material to the estimated fair value amounts. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities are at cost, which approximates fair value due to the short maturity of those instruments. The carrying value of marketable securities is at fair value, which is generally based on quoted market price of the marketable security, and if the quoted market price is not available, the fair value is extrapolated from the quoted market prices of similar marketable securities or by discounting the future cash flows taking into consideration the interest rate probabilities that reflect the risk associated with that marketable security. The carrying value of auction rate securities approximates fair value due to the frequent resetting of the interest rates. The estimated fair value of the convertible senior notes is based on quoted market prices. The carrying value of the amount owed on a secured line of credit with Quest approximates fair value, which is based on discounting the future cash flows using applicable spreads to approximate current interest rates available to the Company.

# Segment Reporting

As a result of the Instrument Business Sale, management has determined that the Company operates one reportable segment, novel diagnostic tests. Prior to the Instrument Business Sale, the Company operated one reportable segment, which was the protein research products and collaborative services business.

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#### Vermillion, Inc. and Subsidiaries

#### Notes to Consolidated Financial Statements (Continued)

## 2. Recent Accounting Pronouncements

#### Accounting for Business Combinations

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, which replaces SFAS No. 141, *Business Combinations*. SFAS No. 141(R) retains the fundamental requirements that the acquisition method of accounting, which was called the purchase method under SFAS No. 141, be used for all business combinations and for an acquirer to be identified for each business combination. SFAS No. 141(R) requires an acquirer to measure the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at their fair values at the acquisition date, with limited exceptions. This replaces the cost-allocation process under SFAS No. 141, which required the cost of an acquisition to be allocated to the individual assets acquired and liabilities assumed based on their estimated fair values. SFAS No. 141(R) also requires the acquirer in a business combination achieved in stages, which is sometimes referred to as a step acquisition, to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values or other amounts determined in accordance with SFAS No. 141(R). SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company is currently evaluating the impact that adopting SFAS No. 141(R) will have on its consolidated financial statements.

# Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities

In June 2007, the Emerging Issues Task Force (the EITF) reached a consensus on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. EITF Issue No. 07-3 requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF Issue No. 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company s adoption of EITF Issue No. 07-3 is not expected to have a material impact on its consolidated financial statements.

## Fair Value Option for Financial Assets and Financial Liabilities

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115.* SFAS No. 159 provides entities with an option to report selected financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company s adoption of SFAS No. 159 is not expected to have a material impact on its consolidated financial statements.

#### Fair Value Measurements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements.

SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years, with early adoption permitted. The Company s adoption of SFAS No. 157 is not expected to have a material impact on its consolidated financial statements.

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#### Vermillion, Inc. and Subsidiaries

#### Notes to Consolidated Financial Statements (Continued)

#### 3. Strategic Alliance with Quest Diagnostics Incorporated

On July 22, 2005, Vermillion and Quest entered into a strategic alliance agreement, which focuses on commercializing up to three diagnostic tests chosen from Vermillion s pipeline. The term of the agreement ends on the later of (i) the three-year anniversary of the agreement and (ii) the date on which Quest commercializes the three diagnostic tests covered by such agreement. Pursuant to the agreement, Quest will have the non-exclusive right to commercialize these tests on a worldwide basis, with exclusive commercialization rights in territories where Quest has a significant presence for up to five years following commercialization. As part of the strategic alliance, there is a royalty arrangement under which Quest will pay royalties to Vermillion based on fees earned by Quest for applicable diagnostics services, and Vermillion will pay royalties to Quest based on Vermillion s revenue from applicable diagnostics products. To date, no such royalties have been earned by either party. In connection with the strategic alliance, Quest purchased 622,500 shares of Vermillion common stock and warrants to purchase up to an additional 220,000 shares of its common stock with an exercise price of \$35.00 per share and expiration date of July 22, 2010, for \$14,954,000 in net proceeds. In connection with Quest s participation in the August 29, 2007, private placement sale, Vermillion amended the warrant originally issued to Quest on July 22, 2005. Pursuant to the terms of the amendment, the exercise price for the purchase of Vermillion s 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 (see further discussion of the private placement sale in Note 12, Common Stock ).

Quest also agreed to provide Vermillion with a \$10,000,000 secured line of credit, which is collateralized by certain intellectual property of Vermillion, that may only be used for certain costs and expenses directly related to the strategic alliance. Under the terms of this secured line of credit, the interest rate is at the prime rate plus 0.5% and is payable monthly. Additionally, this secured line of credit contain provisions for Quest to forgive portions of the amounts borrowed that corresponds to Vermillion s 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 Vermillion 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 commercialization of the first diagnostic test kit; and (iii) \$2,000,000 for each subsequent commercialization of diagnostic test kits with a maximum of two subsequent commercialized diagnostic test kits for \$4,000,000. Should Vermillion fail to achieve these milestones, it would be responsible for the repayment of the outstanding principal amount and any unpaid interest on the secured line of credit on or before July 22, 2010. Vermillion has drawn on this secured line of credit in monthly increments of \$417,000 on the last day of each month during the first two years of the strategic alliance. As of December 31, 2007 and 2006, Vermillion has drawn \$10,000,000 and \$7,083,000, respectively, from this secured line of credit. From the inception of the strategic alliance through December 31, 2007, the Company had spent \$10,000,000 of the amounts drawn on in-house research and development, as well as collaborations with others, directed towards achieving the milestones.

#### 4. Sale of Instrument Business to Bio-Rad Laboratories, Inc.

The Instrument Business Sale to Bio-Rad included the Company s SELDI technology, ProteinChip arrays and accompanying software. Pursuant to the terms of the sales agreement entered into with Bio-Rad, the total sales price was \$20,000,000 of which \$16,000,000 was paid by Bio-Rad to the Company at the closing of the transaction on November 13, 2006, and a total of \$4,000,000 was held back from the sales proceeds contingent upon the Company meeting certain obligations. From the amounts held back, \$2,000,000, subject to certain adjustments, is being held in

escrow until November 13, 2009, to serve as security for Vermillion to fulfill certain obligations. The other \$2,000,000 was withheld by Bio-Rad from the sales proceeds until the issuance of a reexamination certificate confirming United States Patent No. 6,734,022 (the 022 Patent). On October 23, 2007, the United States Patent and Trademark Office issued a reexamination certificate of the 022 Patent, and on November 9, 2007, the Company received \$2,000,000 from Bio-Rad that was withheld from the proceeds of the Instrument Business Sale, which was recorded as a gain on sale of Instrument Business for the year ended December 31, 2007.

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

In connection with the Instrument Business Sale, Vermillion sold 308,642 shares of its common stock to Bio-Rad for \$3,000,000 based on the average closing price of \$9.72 per share for the 5 days preceding the sales agreement on August 14, 2006. In conjunction with the closing of the Instrument Business Sale, the sale of 308,642 shares of Vermillion common stock to Bio-Rad was recorded at its fair value of \$3,611,000, which is based on November 13, 2006, Vermillion s common stock closing price of \$11.70 per share. The \$611,000 difference between the \$3,000,000 sales price and \$3,611,000 fair value is included in the gain on sale of Instrument Business. The calculation of the gain on sale of the Instrument Business at the date of sale was as follows (in thousands):

Cash proceeds	\$ 19,000
Transaction costs	(782)
Net proceeds	18,218
Cost basis:	
Accounts receivable, net and other current assets	2,661
Inventories	4,536
Property, plant and equipment, net	3,231
Other intangible assets	1,856
Goodwill	76
Other long-term assets	152
Accounts payable and accrued liabilities	(1,400)
Deferred revenues	(3,420)
Capital lease obligations	(14)
Value of common stock issued	3,611
Total cost basis	11,289
Gain on sale of Instrument Business	\$ 6,929

In connection with the Instrument Business Sale, Vermillion also entered into a cross-license agreement with Bio-Rad whereby Vermillion retained the royalty-free, exclusive right to commercially exploit existing technology, including SELDI technology, in the clinical diagnostics market for a period of five years after the effective date of the agreement (the Exclusivity Period ), after which the rights become co-exclusive with Bio-Rad. Bio-Rad has the royalty-free, non-exclusive right under Vermillion s retained intellectual property in existence as of the effective date of the agreement to commercially exploit the products, processes and services of the Instrument Business outside of the clinical diagnostics market. Vermillion and Bio-Rad have also granted each other the first right to negotiate in good faith to obtain a non-exclusive, worldwide license on commercially reasonable terms for any improvements created or developed and owned by such party during the exclusivity period for commercialization in the clinical diagnostics market, in the case of Bio-Rad. Bio-Rad also agreed (1) during the exclusivity period, not to sell products or services in the clinical diagnostics market that utilize the SELDI technology or enter into any agreement with any third party to sell any such products or services and (2) not to sell products or services in the clinical diagnostics market that utilize any mass spectrometry

technology, or to enter into any agreement with any third party to sell any such products or services for a specified period after the effective date of the agreement.

Since the Instrument Business Sale, Bio-Rad has taken over Vermillion s manufacturing operations. In connection with the Instrument Business Sale, Vermillion entered into a manufacture and supply agreement with Bio-Rad, whereby Vermillion agreed to purchase from Bio-Rad the ProteinChip Systems and ProteinChip Arrays (collectively referred to herein as the Research Tools Products ) necessary to support Vermillion s diagnostics efforts.

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

Under this agreement, Vermillion must provide Bio-Rad quarterly, non-binding, twelve-month rolling forecasts setting forth Vermillion s anticipated needs for Research Tools Products over the forecast period. Vermillion may provide revised forecasts as necessary to reflect changes in demand for the products, and Bio-Rad is required to use commercially reasonable efforts to supply amounts in excess of the applicable forecast. Under the terms of the manufacture and supply agreement, Vermillion has a commitment to purchase 10 systems and 30,000 arrays in the first year, 13 systems and 30,000 arrays in the second year and 20 systems and 30,000 arrays for the third year in order to support its collaboration agreements with Quest, which may be used as inventory for resale, fixed assets for collaboration purposes or supplies for research and development. The Company has estimated the cost to be \$70,000 per system and \$40 per array for a total estimated obligation of \$6,610,000. If Bio-Rad fails to supply any Research Tools Products to Vermillion, including any new Research Tools Products developed by Bio-Rad for sale to its customers or any new Research Tools Products Vermillion has requested Bio-Rad to make and sell to Vermillion, under certain conditions Vermillion has the right to manufacture or have such Research Tools Products manufactured by a third party for Vermillion s own use and sale to its customers and collaborators in the clinical diagnostics market, subject to payment of a reasonable royalty to Bio-Rad on sales of such Research Tools Products. Vermillion will be responsible for assuring through its incoming quality control process that the Research Tools Products Vermillion purchases from Bio-Rad will comply with applicable government regulations.

The term of this agreement expires on November 12, 2011, but may be renewed for two successive two-year periods at Vermillion's option. Either party may terminate the agreement for convenience upon 180 days prior written notice, or upon default if the other party fails to cure such default within 30 days after notice thereof. Vermillion made total purchases of \$1,032,000 and \$38,000 under this agreement for the years ended December 31, 2007 and 2006, respectively. As of December 31, 2007, Vermillion had a total remaining first year obligation to purchase 4 systems and 13,098 arrays, or \$804,000 based the on estimated costs of \$70,000 per system and \$40 per array. As of December 31, 2007, the Company owed Bio-Rad \$246,000 for Research Tools Products.

In order to allocate support services between Bio-Rad and Vermillion s remaining business following the Instrument Business Sale, Vermillion entered into a transition services agreement with Bio-Rad. Under this agreement, Bio-Rad and the Company agreed to provide each other with certain administrative and operational support and related services and share the use of certain equipment. The term of the agreement was generally six months from the closing of the asset sale but could be extended or shortened with respect to certain items upon mutual agreement by the parties. The agreement was amended in May and June 2007 to extend the term during which the parties would provide certain consulting services to each other until December 31, 2007. Either party may terminate one, some or all of the remaining services of which it is the recipient at any time upon 60 days—advance notice. The parties pay each other a fee for the provision of the consulting services based on an hourly rate tied to the salary of the employee or consultant who is providing such services. For the years ended December 31, 2007 and 2006, transitional services provided by Vermillion to Bio-Rad amounted to \$115,000 and \$66,000, respectively. For the years ended December 31, 2007 and 2006, transitional services provided by Bio-Rad to Vermillion amounted to \$74,000 and \$52,000, respectively.

In connection with the Instrument Business Sale, Vermillion entered into a sublease agreement with Bio-Rad, pursuant to which Vermillion subleases approximately 29,000 square feet of its Fremont, California facility. Bio-Rad may use the sublet premises only for general office, laboratory, research and development, and other uses necessary to conduct their business, and may not sublet the premises without Vermillion s consent. The sublease expires on July 31, 2008, unless terminated earlier in accordance with the terms of the sublease or master lease. Bio-Rad may terminate the sublease at any time upon six months written notice. Rent under the sublease is payable monthly and consists of

base rent plus a proportionate share of certain other expenses including property taxes, management fees, insurance, maintenance and utilities. Rent and certain other facility related expenses are paid directly to Vermillion, and in accordance with the terms of the master lease, all payments received by Vermillion from Bio-Rad under the sublease are paid to the landlord. Under the sublease agreement, Vermillion recognized \$204,000 in base rent and \$25,000 in other rental expenses for the year ended December 31, 2006, and \$1,549,000 in base rent and \$53,000 in other rental expenses for the year ended December 31, 2007.

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#### Vermillion, Inc. and Subsidiaries

## Notes to Consolidated Financial Statements (Continued)

Subsequent to the Instrument Business Sale, both the Company and Bio-Rad recognized business activities on behalf of each other. As of December 31, 2007, the Company owed Bio-Rad \$50,000, which consisted of \$42,000 for accounts receivable the Company collected on behalf of Bio-Rad and \$8,000 for invoices paid by the Company that were reimbursed twice by Bio-Rad. Similarly, Bio-Rad owed the Company \$33,000, which consisted of \$15,000 of invoices paid by the Company on behalf of Bio-Rad and \$18,000 for Bio-Rad s portion of expenses related to facilities shared by the Company. As of December 31, 2006, the Company owed Bio-Rad \$1,571,000, which consisted of \$1,511,000 for accounts receivable the Company collected on behalf of Bio-Rad, \$8,000 for invoices processed by Bio-Rad on behalf of the Company and \$52,000 for services Bio-Rad provided to the Company. Similarly, Bio-Rad owed the Company \$619,000, which consisted of \$174,000 for invoices processed by the Company on behalf of Bio-Rad, \$200,000 for sales taxes on the sale of assets and \$245,000 for unbilled receivables from Bio-Rad. Additionally, for the year ended December 31, 2007, the Company recorded a charge of \$390,000 related to a post-closing adjustment resulting from the Instrument Business Sale, which is reflected in the gain on sale of Instrument Business.

## 5. Short-Term and Long-Term Investments

The Company had no investments in marketable securities at December 31, 2006. At December 31, 2007, the Company s investments consisted of \$12,777,000 invested in auction rate securities, including \$3,902,000 classified as available-for-sale long-term investments as a result of certain auction rate securities failing to settle at auctions subsequent to December 31, 2007. These auction rate securities have a rating of AAA by a major credit rating agency. The Company s available-for-sale short-term and long-term investments consist of the following at December 31, 2007 (in thousands):

	 ortized Cost	Gross Unrealized Gain	Gro Unrea Lo	alized	 Iarket Value
Short-term investments: Auction rate securities	\$ 8,875	\$	\$		\$ 8,875
Long-term investments: Auction rate securities	\$ 4,000	\$	\$	(98)	\$ 3,902

The net unrealized loss on marketable securities available-for-sale was \$98,000 at December 31, 2007. The Company had no sales of marketable securities available-for-sale for the year ended December 31, 2006.

The unrealized loss positions of the Company s available-for-sale short-term and long-term investments at December 31, 2007 were as follows (in thousands):

Less Than 12	12 Months or	
Months	More	Total

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	Fair Value	Gro Unrea Los	alized	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealiz Losse	zed
Short-term investments: Auction rate securities	\$	\$		\$	\$	\$	\$	
Long-term investments: Auction rate securities	\$ 902	\$	(98)	\$	\$	\$ 902	\$ (	(98)
		61						

#### Vermillion, Inc. and Subsidiaries

## **Notes to Consolidated Financial Statements** (Continued)

The scheduled contractual maturity dates for available-for-sale short-term and long-term investments at December 31, 2007, are as follows (in thousands):

	Within 1 Year	After 1 Year through 5 Years	After 5 Year through 10 Years	After Years	ŗ	Γotal
Short-term investments: Auction rate securities	\$	\$	\$	\$ 8,875	\$	8,875
Long-term investments: Auction rate securities	\$	\$	\$	\$ 4,000	\$	4,000

## 6. Property, Plant and Equipment

The components of property, plant and equipment as of December 31, 2007 and 2006, were as follows (dollars in thousands):

	2	2007	2006
Machinery and equipment	\$	4,276	\$ -,
Demonstration equipment		675	649
Leasehold improvements		2,744	2,753
Computer equipment and software		718	720
Furniture and fixtures		183	197
Gross property, plant and equipment		8,596	8,172
Accumulated depreciation and amortization		(6,658)	(5,912)
Property, plant and equipment, net	\$	1,938	\$ 2,260

Depreciation expense for property, plant and equipment was \$1,181,000 and \$3,175,000 for the years ended December 31, 2007 and 2006, respectively.

## 7. Goodwill and Other Intangible Assets

The activity for goodwill and other intangibles for the year ended December 31, 2006, were as follows (in thousands):

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	Goo	odwill	Int	Other tangible Assets	ŗ	Total
Balance at December 31, 2005 Acquired license related to litigation settlement Amortization Write-downs due to the Instrument Business Sale to Bio-Rad	\$	76	\$	2,417 346 (907)	\$	2,493 346 (907)
Laboratories, Inc.		(76)		(1,856)		(1,932)
Balance at December 31, 2006	\$		\$		\$	

In connection with the Instrument Business Sale, Vermillion sublicensed to Bio-Rad certain rights to the core SELDI technology for use outside of the clinical diagnostics field. Vermillion retained exclusive rights to the license rights for use in the field of clinical diagnostics for a five-year period, after which the license will be co-exclusive in this field. The rights to the SELDI technology are derived through royalty-bearing sublicenses from Molecular Analytical Systems, Inc. (MAS). MAS holds an exclusive license to patents directed to the SELDI technology

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

from the owner, Baylor College of Medicine. In 1997, MAS granted certain rights under these patents to Vermillion s wholly owned subsidiaries, IllumeSys Pacific, Inc. and Ciphergen Technologies, Inc. Vermillion obtained further rights under the patents in 2003 through sublicenses and assignments executed as part of the settlement of a lawsuit between Vermillion, MAS, LumiCyte and T. William Hutchens. Together, the sublicenses and assignments provide all rights to develop, make and have made, use, sell, import, market and otherwise exploit products and services covered by the patents throughout the world in all fields and applications, both commercial and non-commercial. The sublicenses carry the obligation to pay MAS a royalty equal to 2% of revenues recognized between February 21, 2003, and the earlier of (i) February 21, 2013, or (ii) the date on which the cumulative payments to MAS have reached \$10,000,000 (collectively the Sublicenses). As of December 31, 2007, Vermillion has paid \$2,597,000 in royalties to MAS under the Sublicenses. Under Vermillion s sublicense agreement with Bio-Rad, Bio-Rad agreed to pay the royalties directly to MAS under the license rights.

#### 8. Accrued Liabilities

The components of accrued liabilities as of December 31, 2007 and 2006, were as follows (dollars in thousands):

	2	007	2	2006
Payroll and related expenses	\$	755	\$	785
Compensated absences		285		320
Collaboration and research agreements expenses		596		1,697
Legal and accounting fees		326		437
Tax-related liabilities		519		637
Accrued interest on convertible senior notes and long-term debt owed to related party		493		185
Current deferred revenue		27		45
Other accrued liabilities		594		539
Total accrued liabilities	\$	3,595	\$	4,645

#### 9. Warranties and Maintenance Contracts

Prior to the Instrument Business Sale, the Company had product warranty activities and obligations to provide services for its products. The Company generally included a standard 12-month warranty on its ProteinChip Systems and certain accessories upon initial sale, after which maintenance and support was available under a separately priced contract or on an individual call basis. The Company also sold separately priced maintenance (extended warranty) contracts, which are generally for 12 or 24 months, upon expiration of the initial 12-month warranty. Coverage under both the standard and extended maintenance contracts were identical. Revenue for both the standard and extended maintenance contracts was deferred and recognized on a straight-line basis over the period of the applicable maintenance contract. Related costs are recognized as incurred.

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

For the year ended December 31, 2007, the Company had no product warranty obligations or activity, as all warranty obligations were assumed by Bio-Rad as of November 13, 2006. Changes in product warranty obligations, including separately priced maintenance obligations, for the year ended December 31, 2006, were as follows (in thousands):

Balance at December 31, 2005	\$ 2,831
Add: Costs incurred for maintenance contracts	1,928
Revenue deferred for maintenance contracts	3,271
Less: Settlements made under maintenance contracts	(1,928)
Revenue recognized for maintenance contracts	(3,896)
Deferred Revenue sold to Bio-Rad Laboratories, Inc.	(2,206)
Balance at December 31, 2006	\$

#### 10. Long-Term Debt

## 7.00% Convertible Senior Notes Due September 1, 2011

On November 15, 2006, Vermillion closed the sale of \$16,500,000 of convertible senior notes due September 1, 2011 (the 7.00% Notes ). Offering costs were \$104,000 and fees of \$514,500, which were paid on behalf of the debt holders, were recorded as debt discount on the 7.00% Notes. Fees paid on behalf of debt holders included the fair value of two warrants issued to underwriters to purchase a total of 20,000 shares of common stock at \$12.60 per share. The warrants were valued at \$140,000 based on the fair value as determined by a Black-Scholes model using the following assumptions: a risk free interest rate of 4.75%, 5 year contractual life, and 88.00% volatility rate. Interest on the 7.00% Notes is 7.00% per annum on the principal amount, payable semiannually on March 1 and September 1 of each year, beginning March 1, 2007. The 7.00% Notes were sold pursuant to separate exchange and redemption agreements between Vermillion and each of Highbridge International LLC, Deerfield International Limited, Deerfield Partners, L.P., Bruce Funds, Inc. and Professional Life & Casualty, each holders of Vermillion s existing 4.50% convertible senior notes due September 1, 2008 (the 4.50% Notes ), 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 through and including the day prior to the closing. The transaction was treated as a debt extinguishment and accordingly, \$613,000 of unamortized prepaid offering costs and \$868,000 of unamortized debt discount related to the 4.50% Notes were charged to expense as loss on extinguishment of debt. The debt discount related to the 7.00% Notes is amortized to interest expense using the effective interest method. The amortization of the debt discount related to the 7.00% Notes amounted to \$195,000 and \$15,000 for the years ended December 31, 2007 and 2006, respectively.

Vermillion issued the 7.00% Notes pursuant to an indenture, dated November 15, 2006, between Vermillion and U.S. Bank National Association, as Trustee. Following the closing, \$2,500,000 in aggregate principal amount of the 4.50% Notes remain outstanding.

The 7.00% Notes are unsecured senior indebtedness of Vermillion and bear interest at the rate of 7.00% per annum, which may be reduced to 4.00% per annum if Vermillion receives approval or clearance for commercial sale of any of

its ovarian cancer tests by the United States Food and Drug Administration (the FDA). Interest is payable on March 1 and September 1 of each year, commencing March 1, 2007. The effective interest rate is 8.18% per annum.

The 7.00% Notes are convertible at the option of each holder, at any time on or prior to the close of business on the business day immediately preceding September 1, 2011, into shares of Vermillion common stock at a conversion price of \$20.00 per share, equivalent to a conversion rate equal to 50 shares of common stock per \$1,000 principal of the 7.00% Notes, subject to adjustment for standard anti-dilution provisions including distributions to common

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

stockholders and stock splits as well as occurrence of a change in control, in which case the conversion rate is adjusted for a make-whole premium.

The make-whole premium shall be equal to the principal amount of 7.00% Notes to be converted divided by \$1,000 and multiplied by the applicable number of shares of common stock based upon Vermillion s share prices as of the change of control date. Specifically, as the 7.00% Notes approach their redemption date of September 1, 2009, as discussed below, the make-whole payment decreases. Vermillion is not required to make a make-whole payment if its stock price is less than \$12.00 or greater than \$80.00 as of the date of the change in control. The make-whole premium associated with the 7.00% Notes sets a maximum additional 1,500,000 shares that may be issued on conversion (90.9091 shares per \$1,000 principal amount of 7.00% Notes).

If a holder converts all or any portion of their 7.00% Notes prior to October 31, 2008, upon such conversion, in addition to the common stock such holder would receive, the holder will be entitled to receive with respect to each 7.00% Note so converted an amount in cash equal to the difference of (i) the amount of all interest that Vermillion would be required to pay on such 7.00% Note from the date of the indenture through October 31, 2008, and (ii) the amount of interest actually paid on such 7.00% Note by Vermillion prior to the time of conversion.

Holders of the 7.00% Notes have the option to require Vermillion to repurchase the 7.00% Notes under certain circumstances, including at any time after September 1, 2009, if Vermillion has not received approval or clearance for commercial sale of any of its ovarian cancer test by the FDA. Vermillion may redeem the 7.00% Notes at its option, in whole or in part, at any time on or after September 1, 2009, at specified redemption prices plus accrued and unpaid interest; provided that the 7.00% Notes will be redeemable only if the closing price of the stock equals or exceeds 200.0% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days ending on the trading day before the date of the notice of the optional redemption. Upon a change of control, each holder of the 7.00% Notes may require Vermillion to repurchase some or all of the 7.00% Notes at specified redemption prices, plus accrued and unpaid interest. The 7.00% Notes contains a put option that entitles the holder to require Vermillion to redeem the 7.00% Note at a price equal to 105.0% of the principal balance upon a change in control of the Company.

Vermillion identified the guaranteed interest payment for any conversion of any 7.00% Note by a holder prior to October 31, 2008, and the written put option permitting the holder to put the debt at 105.0% of principal plus accrued and unpaid interest upon a change of control as a compound embedded derivative, which needs to be separated and measured at its fair value. The factors impacting the fair value of the guaranteed interest payment for any conversion of any 7.00% Note by a holder prior to October 31, 2008, is based upon certain factors including Vermillion s stock price, the time value of money and the likelihood holders would convert within the next two years. However, due to Vermillion s current stock price at the date of 7.00% Note issuance and through December 31, 2007, resulting in the conversion feature being substantially out of the money, the likelihood of conversion was deemed to be remote. The factors impacting the fair value of the written put option permitting the holder to put the 7.00% Note at 105.0% of principal plus accrued and unpaid interest upon a change of control, is contingent upon a change of control. However, due to significant related party holdings of Vermillion s common stock shares and the presence of certain anti-takeover provisions in the bylaws of Vermillion, a change of control is deemed to be remote. When the fair values of these two features are combined, the fair value of the compound embedded derivative had de minimis fair value on the date of inception and through December 31, 2007.

Vermillion and the investors entered into a registration rights agreement in which Vermillion agrees to make reasonable best efforts—to file a shelf registration and keep it effective permitting the 7.00% Note holders to sell the 7.00% Notes or the underlying common stock shares. In the circumstance of a failed registration, Vermillion agrees to pay interest as partial relief for the damages ( Liquidated Damages ) until the earlier of (1) the day on which the registration default has been cured and (2) the date the shelf registration statement is no longer required to be kept effective, in an amount in cash equal to 1.5% of the aggregate outstanding principal amount of the 7.00% Notes until such registration default is cured; provided that in no event shall Liquidated Damages exceed 10.0% of the holder s initial investment in the 7.00% Notes in the aggregate.

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

The Company evaluated the Liquidated Damages according to guidance under FASB Staff Position No. EITF (FSP EITF) 00-19-2, *Accounting for Registration Payment Arrangements*, which specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, shall be recognized and measured separately in accordance with SFAS No. 5, *Accounting for Contingencies*, and FIN 14, *Reasonable Estimation of the Amount of a Loss*. FSP EITF 00-19-2 further states that an entity should recognize and measure a registration payment arrangement as a separate unit of accounting from the financial instrument subject to that arrangement. Accordingly, the Company concluded that the transfer of consideration under a registration payment arrangement is not probable at the time of inception or through December 31, 2007. Therefore a contingent liability under the registration payment arrangement was not recognized.

The 7.00% Notes and common stock issuable upon conversion of the 7.00% Notes were registered with the United States Securities and Exchange Commission (the SEC) on Form S-3 on December 15, 2006, and at December 31, 2007 and 2006, all 7.00% Notes remained issued and outstanding.

#### 4.50% Convertible Senior Notes Due September 1, 2008

On August 22, 2003, the Company closed the sale of \$30,000,000 of the 4.50% Notes. Offering costs were \$1,866,000. Interest on the notes is 4.50% per annum on the principal amount, payable semiannually on March 1 and September 1, beginning March 1, 2004. The effective interest rate is 6.28% per annum. The 4.50% Notes are convertible, at the option of the holder, at any time on or prior to maturity of the 4.50% Notes into shares of the Company s common stock initially at a conversion rate of 10.88329 shares per \$1,000 principal amount of the 4.50% Notes, which is equal to a conversion price of \$91.88 per share. The conversion price, and hence the conversion rate, is subject to adjustment upon the occurrence of certain events, such as stock splits, stock dividends and other distributions or recapitalizations. Because the market value of the stock rose above the conversion price between the day the 4.50% Notes were priced and the closing date, the Company recorded a discount of \$2,677,000 related to the intrinsic value of the beneficial conversion feature resulting from this price change and the fact that the initial purchaser of the 4.50% Notes was not required to purchase the 4.50% Notes until the closing date. Immediately after the closing, Vermillion s common stock had a market price of \$100.10 per share, or \$8.22 per share higher than the conversion price. The value of the beneficial conversion feature was determined by multiplying this difference in the per share price of Vermillion s common stock by the 326,498 underlying shares. This amount is being amortized to interest expense using the effective interest method over the five-year term of the notes, or shorter period in the event of conversion of the 4.50% Notes. The debt discount related to the 4.50% Notes is amortized to interest expense using the effective interest method. The amortization of the beneficial conversion feature amounted to \$44,000 and \$473,000 for the years ended December 31, 2007 and 2006, respectively.

The 4.50% Notes are Vermillion s senior unsecured obligations and rank on parity in right of payment with all of Vermillion s existing and future senior unsecured debt and rank senior to Vermillion s existing and future debt that expressly provides that it is subordinated to the 4.50% Notes. The 4.50% Notes are also effectively subordinated in right of payment to Vermillion s existing and future secured debt, to the extent of such security, and to its subsidiaries liabilities. The indenture does not limit the incurrence by Vermillion or its subsidiaries of other indebtedness.

Vermillion may redeem the 4.50% Notes at its option, in whole or in part, at any time on or after September 1, 2006, at specified redemption prices plus accrued and unpaid interest; provided that the 4.50% Notes will be redeemable

only if the closing price of the stock equals or exceeds 150% 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 redemption. Upon a change of control, each holder of the 4.50% Notes may require Vermillion to repurchase some or all of the 4.50% Notes at specified redemption prices, plus accrued and unpaid interest. The 4.50% Notes contains a put option that entitles the holder to require Vermillion to redeem the 4.50% Notes at a price

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

equal to 105.0% of the principal balance upon a change in control of Vermillion. Vermillion does not anticipate that the put option will have significant value because no change of control is currently contemplated.

The 4.50% Notes and common stock issuable upon conversion of the notes were registered with the SEC on Form S-3 on October 8, 2003. 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. Therefore, the remaining \$2,500,000 in aggregate principal amount of the 4.50% Notes remain outstanding.

## **Equipment Financing Loan**

In June 2003, the Company entered into a loan and security agreement with General Electric Capital Corporation to obtain financing for up to \$5,000,000 of capital equipment purchases. The Company financed \$2,065,000 of capital equipment purchases through this facility at an annual interest rate of 7.48%, repayable in monthly installments over 36 months from the date of each drawdown under the agreement. The loan is collateralized by the equipment being financed as well as certain other assets of the Company. The outstanding loan balance of \$377,000 was paid off in July 2006. Total payments made for this facility including principal and interest were \$450,000 for the year ended December 31, 2006.

#### 11. Commitments and Contingencies

#### **Operating Leases**

Currently, the Company leases various equipment and facilities to support its business of discovering, developing and commercializing diagnostics tests in the fields of oncology, hematology, cardiology and women s health. Prior to November 13, 2006, the Company leased various equipment and facilities to support its worldwide manufacturing, research and development and sales and marketing activities related to the Instrument Business. The Company leases its Fremont facility under a noncancelable operating lease that expires on July 31, 2008. The lease provides for escalations of lease payments of approximately 4% per year and is recognized as rent expense on a straight-line basis. Approximately 29,000 square feet of the Fremont facility has been subleased to Bio-Rad for the remaining lease term (see Note 4, Sale of Instrument Business to Bio-Rad Laboratories, Inc. ). Rental expense under operating leases for the years ended December 31, 2007 and 2006, were as follows (in thousands):

	2007	2006
Gross rental expense Sublease rental income	\$ 3,165 (1,628)	\$ 3,710 (230)
Net rental expense	\$ 1,537	\$ 3,480

As of December 31, 2007, future minimum rental payments under noncancelable operating leases net of aggregate minimum noncancelable sublease rentals are as follows (in thousands):

2008 2009	\$ 2,030 9
Total minimum rental payments Total sublease rentals	2,039 (695)
Net rental payments	\$ 1,344
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#### Vermillion, Inc. and Subsidiaries

#### Notes to Consolidated Financial Statements (Continued)

#### Noncancelable Collaboration Obligations and Other Commitments

The research collaboration agreement with The Johns Hopkins University School of Medicine (JHU), which was extended through December 31, 2007, was 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. As of December 31, 2007, Vermillion had a remaining obligation of \$150,000 related to the research collaboration agreement extension with JHU. Collaboration costs, which are included in research and development expenses, related to these extended research collaboration agreement were \$368,000 and \$964,000 for the years ended December 31, 2007 and 2006, respectively.

On September 22, 2005, Vermillion entered into a two year collaborative research agreement with University College London and UCL Biomedica Plc (collectively referred to as UCL ), which expired on September 30, 2007. The collaborative research agreement was directed at the utilization of Vermillion s former suite of proteomic solutions to further both parties ongoing research in ovarian cancer and breast cancer. Under the terms of the agreement, Vermillion had exclusive rights to license intellectual property resulting from discoveries made during the course of this collaboration for use in developing, manufacturing and commercializing products and services utilizing the intellectual property. Under the terms of the collaborative research agreement, Vermillion had a noncancelable obligation to contribute £604,000 in the first year of the agreement. In the second year of the agreement, which was cancelable with three months advance notice, Vermillion had an obligation to contribute cash of £605,000. As of December 31, 2007, Vermillion has paid £816,000 or \$1,603,000 and had a remaining cash obligation of £393,000 or \$827,000 related to this agreement. Additionally, under the terms of the collaborative research agreement, Vermillion had a noncancelable obligation to provide equipment, software, arrays and consumable supplies with an estimated value at Vermillion s list selling price of £370,000 to cover part of the costs incurred by UCL specifically for this research program. As of December 31, 2007, Vermillion had provided at its cost \$112,000, or \$546,000 valued at Vermillion s list selling price, of equipment, software, arrays and consumable supplies to UCL. Collaboration costs, which are included in research and development expenses, related to this agreement were \$1,105,000 and \$1,083,000 for the years ended December 31, 2007 and 2006, respectively.

On October 4, 2006, Vermillion entered into a one-year research and development agreement, which has automatic renewals for two additional one-year terms, with Katholieke Universiteit Leuven, Belgium, directed at discovery, validation and characterization of novel biomarkers related to gynecologic disease. Under the terms of the agreement, Vermillion has exclusive rights to license discoveries made during the course of this collaboration. Under the terms of the research and development agreement, Vermillion had a noncancelable obligation of 45,000 in the first year of the agreement to fund sample collection at the Katholieke Universiteit Leuven from patients undergoing evaluation of a persistent mass who will undergo surgical intervention. As of December 31, 2007, the Company has paid 45,000 or \$61,000 related to this agreement. Collaboration costs, which are included in research and development expenses, related to this agreement were \$61,000 for the year ended December 31, 2007.

On October 13, 2006, the Company entered into a two year research and collaboration agreement, which has automatic renewals of additional one-year terms, with The Ohio State University Research Foundation (OSU) directed at discovery, purification, identification and/or validation of biomarkers related to thrombotic thrombocytopenic purpura (TTP) and production of associated technology. Under the terms of the agreement, Vermillion has an option to take an exclusive license to discoveries made during the course of this collaboration. During the first fifteen months of the agreement, Vermillion had a total noncancelable obligation of \$150,000 to OSU in consideration for costs

incurred specifically for this research program. As of December 31, 2007, the Company has paid \$120,000 and had a remaining obligation of \$30,000 related to this agreement. Collaboration costs, which are included in research and development expenses, related to this agreement were \$120,000 and \$30,000 for the years ended December 31, 2007 and 2006, respectively.

On December 11, 2006, Vermillion entered into a consulting agreement with PrecisionMed International (PrecisionMed), which was subsequently amended on April 5, 2007. Under the terms of the amended agreement,

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

PrecisionMed collected whole blood specimens from up to 1,000 research subjects for the purposes of Vermillion s whole blood collection protocol for its ovarian tumor triage test clinical trial. The amended agreement provided for a maximum payment of \$1,335,000 for 500 research subjects and a maximum payment of \$1,788,000 for 1,000 research subjects. As of December 31, 2007, Vermillion has paid a total of \$1,433,000, including travel expenses of \$50,000, related to this agreement. These costs, which are included in research and development expenses, related to this agreement were \$972,000 and \$461,000 for the years ended December 31, 2007 and 2006, respectively.

On June 1, 2007, Vermillion entered into a nonexclusive license agreement with the National Cardiovascular Center ( NCVC ), an entity organized and existing under the laws of Japan. Under this agreement, Vermillion obtained a ten-year worldwide nonexclusive license with the right to extend the term for the life of the licensed patent, which includes a United States Patent Application, a Japan Patent and a Patent Cooperation Treaty ( PCT ) Application, for technology used in Vermillion s TTP diagnostic test kit that is under development. Under this agreement, Vermillion will pay NCVC a non-refundable license fee of \$50,000. The payment terms are \$20,000 upon execution of this agreement, \$10,000 upon submission of an in vitro diagnostic test to the FDA for clearance, \$10,000 upon the first commercial sale of such in vitro diagnostic test kit and \$10,000 upon achievement of \$500,000 in net sales of such in vitro diagnostic test kits. Additionally, Vermillion will pay royalties to NCVC for net sales to customers located in the United Sates, Japan, Europe and China. As of December 31, 2007, Vermillion has paid \$20,000 related to the execution of this agreement.

In connection with the Instrument Business Sale, Vermillion entered into a manufacture and supply agreement with Bio-Rad, whereby Vermillion agreed to purchase Research Tools Products from Bio-Rad (see Note 4, Sale of Instrument Business to Bio-Rad Laboratories, Inc. ). Under the terms of the manufacture and supply agreement, Vermillion has a commitment to purchase 10 systems and 30,000 arrays in the first year, 13 systems and 30,000 arrays in the second year and 20 systems and 30,000 arrays for the third year. The Company has estimated the cost to be \$70,000 per system and \$40 per array for a total estimated obligation of \$6,610,000. Vermillion made total purchases of \$1,032,000 and \$38,000 under this agreement for the years ended December 31, 2007 and 2006, respectively. As of December 31, 2007, Vermillion had a total remaining first year obligation to purchase 4 systems and 13,098 arrays, or \$804,000 based the on estimated costs of \$70,000 per system and \$40 per array. As of December 31, 2007, the Company owed Bio-Rad \$246,000 for Research Tools Products.

#### Litigation

On September 17, 2007, MAS filed a lawsuit in the Superior Court of California for the County of Santa Clara naming Vermillion and Bio-Rad as defendants. Under the lawsuit, MAS seeks an unspecified amount of damages and alleges, among other things, that Vermillion is in breach of its license agreement with MAS relating to SELDI technology as a result of Vermillion s entry into a sublicense agreement with Bio-Rad. In connection with the Instrument Business Sale, Vermillion sublicensed to Bio-Rad certain rights to the SELDI technology that Vermillion obtained under the MAS license for use outside of the clinical diagnostics field. Vermillion retained exclusive rights to the technology for use in the field of clinical diagnostics for a five-year period, after which it will retain nonexclusive rights in that field. Vermillion is deadline to answer or otherwise respond to the Complaint is April 1, 2008. Vermillion intends to vigorously defend this action. Given the early stage of this action, management cannot predict the ultimate outcome of this matter at this time.

On June 26, 2006, Health Discovery Corporation ( HDC ) filed a lawsuit against Vermillion in the United States District Court for the Eastern District of Texas, Marshall Division (the Court ), claiming that software used in certain Vermillion ProteinChip Systems infringes on three of its United States patents. HDC sought injunctive relief as well as unspecified compensatory and enhanced damages, reasonable attorney s fees, prejudgment interest and other costs. On August 1, 2006, Vermillion filed an unopposed motion with the Court to extend the deadline for Vermillion to answer or otherwise respond until September 2, 2006. Vermillion filed its answer and counterclaim to the complaint with the Court on September 1, 2006. Concurrent with its answer and counterclaims, Vermillion filed a motion to transfer the case to the Northern District of California. On January 10, 2007, the Court granted

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

Vermillion s motion to transfer the case to the Northern District of California. The parties met for a scheduled mediation on May 7, 2007. On July 10, 2007, Vermillion entered into a license and settlement agreement with HDC (the HDC Agreement ) pursuant to which it licensed more than 25 patents covering HDC s support vector machine technology for use with Surface Enhanced Laser Desorption/Ionization (SELDI) technology. Under the terms of the HDC Agreement, Vermillion receives a worldwide, royalty-free, non-exclusive license for life sciences and diagnostic applications of the technology and it has access to any future patents resulting from the underlying intellectual property in conjunction with use of SELDI systems. Pursuant to the HDC Agreement, Vermillion paid to HDC \$200,000 upon entry into the agreement on July 10, 2007, and \$100,000 three months following the date of the agreement on October 10, 2007. The remaining \$300,000 under the HDC Agreement is payable as follows: \$150,000 twelve months following the date of the agreement. The total settlement of \$600,000 was expensed for the year ended December 31, 2007. The HDC Agreement settled all disputes between Vermillion and HDC.

In addition, from time to time, the Company is involved in legal proceedings and regulatory proceedings arising out of its operations. The Company establishes reserves for specific liabilities in connection with legal actions that it deems to be probable and estimable. No amounts have been accrued in the consolidated financial statements with respect to any pending litigation. The Company is not able to make a reasonable estimate of any liability due to the uncertainties related to the outcome and the amount or range of loss. Other than as disclosed above, the Company is not currently a party to any proceeding, the adverse outcome of which would have a material adverse effect on the Company s financial position or results of operations.

#### 12. Common Stock

#### Stockholders Rights Plan

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

The rights issued pursuant to Vermillion s Stockholder Rights Plan will become exercisable the tenth day after a person or group announces acquisition of 15% or more of Vermillion s common stock or announces commencement of a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of Vermillion s common stock. If the rights become exercisable, the holders of the rights (other than the person acquiring 15% or more of Vermillion s common stock) will be entitled to acquire, in exchange for the rights exercise price, shares of Vermillion s common stock or shares of any company in which the Company is merged, with a value equal to twice the rights exercise price.

#### **Authorized Shares**

At the annual stockholders meeting on June 29, 2007, the stockholders approved an amendment to the Certificate of Incorporation to increase the number of authorized shares of common stock from 80,000,000 to 150,000,000. On

July 13, 2007, the Company amended and restated its Certificate of Incorporation with the State of Delaware for the increased authorized shares. Additionally, after the Reverse Stock Split the number of authorized shares of common stock and preferred stock remained at 150,000,000 and 5,000,000, respectively.

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

#### Private Placement Sale

On August 29, 2007 (the Closing Date ), Vermillion completed a private placement sale of 2,451,309 shares of its common stock and warrants to purchase up to an additional 1,961,047 shares of its 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. Existing investors included affiliates of the Company, who purchased 964,285 shares of Vermillion common stock and warrants to purchase up to an additional 771,428 shares of Vermillion common stock for \$8,100,000. In connection with Quest s participation in this transaction, Vermillion amended a warrant originally issued to Quest on July 22, 2005. Pursuant to the terms of the amendment, the exercise price for the purchase of Vermillion s 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. For services as placement agent, Vermillion paid Oppenheimer & Co. Inc. (Oppenheimer) \$1,200,000 and issued a warrant to purchase up to 92,100 shares of Vermillion s common stock with an exercise price of \$9.25 per share and expiration date of August 29, 2012. The warrants issued to the investors and Oppenheimer were valued at \$7,194,000 and \$581,000, respectively, based on the fair value as determined by the Black-Scholes model. The amended value of the warrant issued to Quest on July 22, 2005, increased by \$356,000, which is reflected in additional paid-in capital, from the its original value of \$2,200,000. Assumptions used to value the warrants issued to the investors and Oppenheimer, and the amended value of the warrant issued to Quest were as follows:

	Private Investors and Oppenheimer & Co. Inc.	Amendment to Quest Diagnostics Incorporated
Dividend yield	%	%
Volatility	80.14%	82.92%
Risk-free interest rate	4.31%	4.24%
Expected lives (years)	5.00	3.90

Under the terms of the securities purchase agreement, the Company is required to prepare and file with the SEC a Shelf Registration Statement and have the Registration Statement be declared effective by the SEC. The Company shall pay each investor liquidated damages of 1/13 of 1.5% of the aggregate purchase price with respect to any shares not previously sold or transferred for the following events:

Each day in excess of 30 days from the Closing Date until the Shelf Registration Statement is filed with the SEC.

Each day in excess of 90 days from the Closing Date until the Registration Statement is declared effective by the SEC if no SEC review of the Shelf Registration Statement, or each day in excess of 120 days from the Closing Date until the Registration Statement is declared effective by the SEC in the event of an SEC review of the Registration Statement.

Each day for a period in excess of 20 consecutive days or 45 total days in any 12-month period that the SEC issues a stop order to suspend the effectiveness of the Registration Statement.

The maximum cumulative liquidated damages are 10.0% of the aggregate purchase price. Payment of liquidated damages is due 30 days after coming into compliance with above events. Interest is 1.5% every 30 days for delinquent payments.

The Company evaluated the liquidated damages provision according to guidance under FSP EITF 00-19-2, which specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, shall be recognized and measured separately in accordance with SFAS No. 5 and FIN 14. FSP EITF 00-19-2 further states that an entity should recognize and measure a registration payment

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

arrangement as a separate unit of account from the financial instrument subject to that arrangement. The Company filed a Form S-1, Shelf Registration Statement, with the SEC on September 27, 2007, which became effective on December 13, 2007. The Company considers the likelihood of the SEC suspension of the effectiveness of the Registration Statement for a period of 20 consecutive days or not more than 45 days in any 12-month period to be remote. As a result, to date no contingent liability was recorded related to this registration payment arrangement. As of December 31, 2007, the Company had incurred costs of \$2,245,000 in connection with the registration of these securities, which is reflected as a reduction to additional paid-in capital.

## 13. Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of December 31, 2007 and 2006, were as follows (in thousands):

	2007	2006	
Net unrealized loss on long-term investments available-for-sale Cumulative translation adjustment	\$ (98) (123)	\$ (71)	
Accumulated other comprehensive loss	\$ (221)	\$ (71)	

#### 14. Loss Per Share

The reconciliation of the numerators and denominators of basic and diluted earnings per share for the years ended December 31, 2007 and 2006, was as follows (dollars in thousands, except shares and per share amounts):

	Loss (Numerator)		Shares (Denominator)	Per Share Amount	
Year ended December 31, 2007:  Net loss basic  Dilutive effect of shares purchasable under the Employee Stock  Purchase Plan, stock options, warrants and convertible senior notes	\$	(21,282)	4,765,341	\$	(4.47)
Net loss diluted	\$	(21,282)	4,765,341	\$	(4.47)
Year ended December 31, 2006:  Net loss basic  Dilutive effect of common stock shares issuable upon exercise of stock options, purchase by Employee Stock Purchase Plan, exercise of warrants and conversion of convertible senior notes	\$	(22,066)	3,646,473	\$	(6.05)

Net loss diluted \$ (22,066) 3,646,473 \$ (6.05)

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#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

Due to net losses for the years ended December 31, 2007 and 2006, 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, 2007 and 2006, were as follows:

	2007	2006
Stock options	469,675	476,581
Employee Stock Purchase Plan	2,786	2,893
Stock warrants	2,293,147	240,000
Convertible senior notes	852,208	852,208
Potential common shares	3,617,816	1,571,682

#### 15. Employee Benefit Plans

#### 1993 Stock Option Plan

Vermillion has no shares of its common stock reserved for sale to employees, directors or consultants under its 1993 Stock Option Plan (the 1993 Plan ). Under the 1993 Plan, options were granted at prices not lower than 85% and 100% of the fair market value of the common stock for nonstatutory and statutory stock options, respectively. All outstanding options under the 1993 Plan are now fully vested, and unexercised options generally expire ten years from the date of grant. At December 31, 2007 and 2006, no shares of Vermillion common stock were subject to repurchase by Vermillion. Since Vermillion s initial public offering, no options have been granted under the 1993 Plan. There were no option exercises for the year ended December 31, 2007, and options for 1,825 shares of Vermillion common stock were exercised for the year ended December 31, 2006.

#### 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 nonstatutory 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. At December 31, 2007, Vermillion had 6,776,983 shares of its common stock reserved for future stock option grants to employees, directors and consultants under the 2000 Plan. Options for 2,031 shares and 660 shares were exercised, for the years ended December 31, 2007 and 2006, respectively.

In conjunction with the Reverse Stock Split, an additional 6,525,000 shares of Vermillion common stock were reserved for issuance under the 2000 Plan for the year ended December 31, 2007. No additional shares of Vermillion common stock were reserved for issuance under the 2000 Plan for the year ended December 31, 2007. On January 1, 2006, an additional 130,000 shares of Vermillion common stock were reserved for issuance under the 2000 Plan.

#### Employee Stock Purchase Plan

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

ESPP provides for the purchase of Vermillion common stock at the lower of 85.00% of the closing price of Vermillion common stock on the first day of the offering period or 85.00% of the closing price of Vermillion common stock on the last day of the offering period. In conjunction with the Reverse Stock Split, an additional 1,355,215 shares of Vermillion common stock were reserved for issuance under ESPP for the year ended December 31, 2007. No additional Vermillion common stock shares were reserved for issuance under ESPP for the year ended December 31, 2007. On January 1, 2006, an additional 17,000 shares of Vermillion common stock were reserved for issuance under ESPP.

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#### Vermillion, Inc. and Subsidiaries

## Notes to Consolidated Financial Statements (Continued)

## **Stock-Based Compensation**

In estimating the fair value of each stock option award on their respective grant dates and stock purchased under ESPP, the Company uses the Black-Scholes pricing model. The Black-Scholes pricing model requires the Company to make assumptions with regard to the options granted and stock purchased under ESPP during a reporting period namely, expected life, stock price volatility, expected dividend yield and risk-free interest rate.

The expected life of options is based on historical data of Vermillion s actual experience with the options it has 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 the historical volatility of Vermillion s common stock for the year ended December 31, 2007. The historical volatility covers a period that corresponds to the expected life of the options. For the year ended December 31, 2006, the Company used a combination of historical and peer group volatility for a blended volatility in deriving its expected volatility assumption as allowed under SFAS No. 123(R) and the SEC s Staff Accounting Bulletin (SAB) No. 107. At that point in time, the Company made an assessment that blended volatility is more representative of future stock price trends than just using historical or peer group volatility. The expected dividend yield is based on the estimated annual dividends that Vermillion expects to pay over the expected life of the options as a percentage of the market value of Vermillion s 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.

The expected life of shares purchased under ESPP is six months, which corresponds to the offering period. The expected stock price volatility is estimated using a six-month historical volatility of Vermillion s common stock, which corresponds to the offering period. The expected dividend yield is based on the estimated annual dividends that Vermillion expects to pay over the expected life of shares purchased under ESPP as a percentage of the market value of Vermillion s common stock as of the grant date. The risk-free interest rate for the expected life of the shares purchased under ESPP is based on the United States Treasury yield curve in effect as of the beginning of the offering period.

The average assumptions used to calculate the fair value of options granted and shares purchasable under ESPP that were incorporated in the Black-Scholes pricing model for the years ended December 31, 2007 and 2006, were as follows:

		2000 Stock Plan			Employee Stock Purchase Plan			
	,	2007		2006	2	2007	2	2006
Dividend yield		%		%		%		%
Volatility		81.46%		86.23%		83.30%		84.55%
Risk-free interest rate		4.81%		4.80%		4.78%		4.96%
Expected lives (years)		5.20		6.07		0.50		0.50
Weighted average fair value	\$	8.55	\$	9.02	\$	4.84	\$	6.30

# Vermillion, Inc. and Subsidiaries

### **Notes to Consolidated Financial Statements** (Continued)

The activity related to shares available for grant under the 1993 Plan, 2000 Plan and ESPP for the years ended December 31, 2007 and 2006, were as follows:

			2000 Employee	
	1993 Stock Option	2000	Stock	
	Plan	Stock Plan	Purchase Plan	Total
Shares available at December 31, 2005		25,930	16,650	42,580
Additional shares reserved		130,000	17,000	147,000
Options canceled	37,198	274,033		311,231
Reduction in shares reserved	(37,198)			(37,198)
Options granted		(156,945)		(156,945)
Shares purchased			(11,029)	(11,029)
Shares available at December 31, 2006		273,018	22,621	295,639
Additional shares reserved		6,525,000	1,355,215	7,880,215
Options canceled	25,910	153,735		179,645
Reduction in shares reserved	(25,910)			(25,910)
Options granted		(174,770)		(174,770)
Shares purchased			(4,813)	(4,813)
Shares available at December 31, 2007		6,776,983	1,373,023	8,150,006

The stock option activity under the 1993 Plan and 2000 Plan for the years ended December 31, 2007 and 2006, was as follows (dollars are in thousands, except weighted average exercise price):

	Number of Shares	A: E:	eighted verage xercise Price	Ì	ggregate ntrinsic Value	Weighted Average Remaining Contractual Term
Options outstanding at December 31, 2005 Granted	633,352 156,945	\$	44.61 12.04	\$	28,256 1,890	7.71
Exercised Canceled	(2,485) (311,231)		4.92 41.60		(12) (12,948)	
Options outstanding at December 31, 2006 Granted	476,581 174,770	\$	36.06 12.41		17,186 2,169	7.60

Exercised Canceled	(2,031) (179,645)	11.85 38.84	(24) (6,978)	
Options outstanding at December 31, 2007	469,675	\$ 26.30	\$ 12,353	7.72
Shares exercisable: December 31, 2007 December 31, 2006	272,162 304,652	\$ 36.44 48.52	\$ 9,919 14,781	6.84 6.74
	75			

### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

The range of exercise prices for options outstanding and exercisable at December 31, 2007, are as follows:

	Options	A	eighted verage xercise	Weighted Average Remaining Life in	Options	A	eighted verage xercise
Exercise Price	Outstanding	]	Price	Years	Exercisable	]	Price
\$ 8.80 - \$ 9.00	68,500	\$	8.98	8.19	40,500	\$	9.00
\$ 9.01 - 10.10	47,900		9.54	9.41	1,294		9.95
\$10.11 - \$11.63	25,934		10.34	8.88	12,313		10.50
\$11.64 - \$12.00	75,250		12.00	8.34	42,812		12.00
\$12.01 - \$13.60	11,460		13.29	9.00	988		13.00
\$13.61 - \$14.70	69,000		14.70	9.32	11,500		14.70
\$14.71 - \$21.90	53,790		20.42	7.14	48,526		20.70
\$21.91 - \$48.60	47,048		37.01	4.83	43,436		37.02
\$48.61 - \$96.00	70,793		86.22	5.61	70,793		86.22
\$8.80 - \$96.00	469,675	\$	26.30	7.72	272,162	\$	36.44

The allocation of stock-based compensation expense by functional area for the years ended December 31, 2007 and 2006, was as follows (in thousands):

	2007	2	2006
Cost of revenue	\$	\$	144
Research and development	167		337
Sales and marketing	88		321
General and administrative	623		813
Total	\$ 878	\$	1,615

The Company has a 100% valuation allowance recorded against its deferred tax assets, and as a result SFAS No. 123(R) had no effect on income tax expense in the consolidated statement of operations or the consolidated statement of cash flows. As of December 31, 2007, total unrecognized compensation cost related to nonvested stock option awards was \$1,456,000 and the related weighted average period over which it is expected to be recognized was 2.88 years.

### Ciphergen Biosystems, Inc. 401(k)

The Company maintains the Ciphergen Biosystems, Inc. 401(k) Plan (the 401(k) Plan ) for its United States employees. The 401(k) Plan allows eligible employees to defer up to an annual limit of the lesser of 90% of eligible compensation or a maximum contribution amount subject to the Internal Revenue Service annual contribution limit,. The Company is not required to make contributions under the 401(k) Plan. As of December 31, 2007, the Company has not contributed to the 401(k) Plan.

### 16. Income Taxes

The Company accounts 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 tax bases of assets and liabilities using the current tax laws and rates. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The provision for income taxes was due to foreign income taxes, which were \$163,000 and \$152,000 for the years ended December 31, 2007 and 2006, respectively.

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### Vermillion, Inc. and Subsidiaries

# **Notes to Consolidated Financial Statements** (Continued)

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, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2007.

The components of deferred tax assets (liabilities) at December 31, 2007 and 2006, were as follows (in thousands):

	2	2007	2006
Deferred tax assets:			
Depreciation and amortization	\$	18,236	\$ 21,515
Other		4,575	4,093
Research and development and other credits		3,610	9,145
Net operating loses		17,152	46,999
Total deferred tax assets		43,573	81,752
Valuation allowance	(	43,573)	(81,752)
Net deferred tax assets	\$		\$
Deferred tax liabilities:			
Investment in foreign subsidiaries	\$	(259)	\$

The reconciliation of the statutory federal income tax rate to the Company s effective tax rate for the years ended December 31, 2007 and 2006, was as follows:

	2007	2006
Tax at federal statutory rate	(34)%	(34)%
State tax, net of federal benefit	(6)	
Foreign loss		(5)
Research and development credits	(1)	2
Deferred tax assets not benefited	(181)	35
Stock based compensation	1	2
Foreign rate difference and other		1
Net operating loss and credit reduction due to Section 382 limitations	222	
Effective income tax rate	1%	1%

As of December 31, 2007, the Company has net operating loss carryforwards of \$40,332,000 for federal and \$43,730,000 for state income tax purposes. If not utilized, these carryforwards will begin to expire in 2009 for federal

purposes and 2008 for state purposes.

As of December 31, 2007, the Company has \$2,609,000 of net operation carryforwards from its Japan operations. If not utilized, this carry forward will begin to expire in 2012.

The Company has research credit carryforwards of \$109,000 and \$4,918,000 for federal and state income tax purposes, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2017. The California credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where equity transactions resulted in a change of ownership by Internal Revenue Code 382. During the year ended December 31, 2007, the Company conducted a study and determined that Company s use of its net operating loss and federal credits is subject to such a restriction. Accordingly, the Company reduced its deferred tax assets and the corresponding valuation allowance by \$46,826,000. As a result, the net operating loss and federal

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#### Vermillion, Inc. and Subsidiaries

### **Notes to Consolidated Financial Statements** (Continued)

credit amounts as of December 31, 2007, reflect the restriction on the Company s ability to use the net operating loss and credits.

Pursuant to paragraph 31 of SFAS No. 109, a deferred tax liability should be recognized if the excess of book basis over tax basis of an investment in a foreign subsidiary is expected to reverse in the foreseeable future. Since Vermillion is in the process of liquidating all of its foreign subsidiaries except for Ciphergen Biosystems KK, the Company anticipates the basis difference to reverse in the foreseeable future. As such, a deferred tax liability was recorded for the excess of book basis over the tax basis of the Company s investment in those foreign subsidiaries being liquidated.

#### 17. Fair Value of Financial Instruments

The convertible senior notes carrying value and estimated fair value at December 31, 2007 and 2006, were as follows (in thousands):

	2	007	2006			
	Carrying	Estimated	Carrying	Estimated		
	Amount	Fair Value	Amount	Fair Value		
4.50% convertible senior notes due September 1, 2008 7.00% convertible senior notes due September 1, 2011	\$ 2,471	\$ 2,450	\$ 2,427	\$ 1,456		
	16,196	14,850	16,001	13,201		
Total	\$ 18,667	\$ 17,300	\$ 18,428	\$ 14,657		

#### 18. Supplemental Cash Flow Information

The supplemental cash flow information for the years ended December 31, 2007 and 2006, was as follows (dollars in thousands):

	2007	2006
Cash paid during the period for:		
Interest	\$ 1,807	\$ 1,732
Income taxes	214	227
Noncash investing and financing activities:		
Transfer of fixed assets to (from) inventory	\$	\$ (793)

#### 19. Geographic Information

Prior to November 13, 2006, the Company sold its products and services directly to customers in North America, Western Europe and Japan, and through distributors in other parts of Europe and Asia, and in Australia. Revenue for

geographic regions reported below is based upon the customers locations. The following is a summary of the geographic information related to revenue for the years ended December 31, 2007 and 2006 (in thousands):

	2007	2006
United States Canada Europe Asia-Pacific	\$ 44	\$ 5,155 973 6,984 5,103
Total	\$ 44	\$ 18,215
78	3	

#### Vermillion, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements** (Continued)

Sales to customers in Japan were 23.4% of revenue for the year ended December 31, 2006. No other country outside the United States accounted for 10.0% or more of total revenue during this period.

Long-lived assets, primarily machinery and equipment, are reported based on the location of the assets. Long-lived asset information by geographic area as of December 31, 2007 and 2006, were as follows (in thousands):

	2007	2006
United States Europe	\$ 1,938	\$ 2,244 16
Total	\$ 1,938	\$ 2,260

### 20. Subsequent Events

On January 30, 2008, Vermillion renewed its research collaboration agreement with JHU. The agreement has an effective period from January 1, 2008, through December 31, 2010, with automatic one-year extensions for up to three additional years unless terminated by Vermillion or JHU. Under the terms of the research collaboration agreement, Vermillion is required to pay noncancelable contributions of \$600,000, \$618,000 and \$637,000 for the years ending December 31, 2008, 2009 and 2010, respectively. In conjunction with the renewed collaboration agreement, Vermillion also amended and restated the patent license agreement with JHU, which grants Vermillion an exclusive worldwide license to any inventions resulting from the research related to biomarkers for ovarian cancer. Under the terms of the amended and restated patent license agreement, Vermillion is required to pay annual noncancelable minimum royalties of \$50,000 for years ending December 31, 2008, 2009 and 2010, and royalties on net sales and sublicensing consideration received by Vermillion related to ovarian diagnostic test kits.

As of March 24, 2008, the Company s entire investment portfolio of \$6,500,000 was invested in auction rate securities, which failed to settle at auctions from January 1, 2008, to March 24, 2008, due to the current overall credit concerns in the capital markets, and are classified as available-for-sale long-term investments. The investment portfolio at March 24, 2008, consists of \$3,902,000 of auction rate securities classified as available-for-sale long-term investments at December 31, 2007, and an additional \$2,500,000 of auction rate securities purchased during January and February 2008, which failed to settle at auctions during March 2008. These auction rate securities provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, which is generally every 28 days. The failure of the auctions impact the Company s ability to readily liquidate its auction rate securities into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument. The Company continues to earn interest on the investments that failed to settle at auction, at the maximum contractual rate. The Company will continue to monitor the value of its auction rate securities each reporting period for a possible impairment if a decline in fair value occurs.

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### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

#### Item 9A(T). Controls and Procedures

Disclosure Controls and Procedures. Vermillion, Inc. (Vermillion; Vermillion and its wholly owned subsidiaries are collectively referred to as the Company), formerly known as Ciphergen Biosystems, Inc., has carried out an evaluation, under the supervision and with the participation of the Company s management, including Vermillion s Chief Executive Officer and Interim Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures as of December 31, 2007, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act ). Based upon that evaluation, Vermillion s Chief Executive Officer and Interim Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective as of December 31, 2007.

Management s Report on Internal Control over Financial Reporting. The Company s management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Rule 13a-15(f) under the Exchange Act, internal control over financial reporting is a process designed by or under the supervision of a company s principal executive and principal financial officers, and effected by a company s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. It includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of a company;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of a company are being made only in accordance with authorizations of management and board of directors of a company; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of a company s assets that could have a material effect on its financial statements.

Management has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2007. In making its assessment of internal control, management used the criteria described in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission.

As a result of its assessment, management has concluded that the Company s internal control over financial reporting was effective as of December 31, 2007.

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.

This Annual Report on Form 10-K does not include an attestation report of the Company s independent registered public accounting firm regarding internal control over financial reporting. Management s assessment of the effectiveness of the Company s internal control over financial reporting as of December 31, 2007, was not subject to attestation by the Company s independent registered public accounting firm pursuant to temporary rules of the United States Securities and Exchange Commission that permit the Company to provide only management s report in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting. The Company has made no change in its internal control over financial reporting that has materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting during the three months ended December 31, 2007.

Item 9B. Other Information

None.

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#### **PART III**

### Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to Vermillion, Inc. s (Vermillion) executive officers, directors, the Audit Committee financial expert and the Audit Committee is incorporated by reference from the information contained in the section captioned Proposal No. 1 Election of Three Class II Directors , Executive Compensation and Other Matters - Executive Officers in 2007 , Board Meetings and Committees Audit Committee and Audit Committee Report Section 16(a) Beneficial Ownership Reporting Compliance in Vermillion s definitive Proxy Statement for the June 11, 2008, Annual Meeting of Stockholders (the Definitive Proxy Statement ).

The information required by this item with respect to Vermillion s Code of Ethics are incorporated by reference from the information contained in the section captioned Board Meetings and Committees Code of Ethics in the Definitive Proxy Statement. The Code of Ethics is available to the public on Vermillion s website at <a href="https://www.vermillion.com">www.vermillion.com</a>. If Vermillion makes any substantive amendments to the Code of Ethics, or grant any waiver, including any implicit waiver, from a provision of the Code of Ethics to its Chief Executive Officer, Chief Financial Officer or Corporate Controller, Vermillion will disclose the nature of such amendment or waiver on its website.

#### Item 11. Executive Compensation

The information required by this item with respect to Vermillion, Inc. s executive officers and directors is incorporated by reference from the information contained in the sections captioned Executive Officer Compensation and Other Matters in Vermillion, Inc. s definitive Proxy Statement for the June 11, 2008, Annual Meeting of Stockholders.

#### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference from the information contained in the sections captioned Security Ownership of Certain Beneficial Owners and Management in Vermillion, Inc. s definitive Proxy Statement for the June 11, 2008, Annual Meeting of Stockholders.

### Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from the information contained in the section captioned Audit Committee Report Certain Business Relationships and Related Party Transactions in Vermillion, Inc. s definitive Proxy Statement for the June 11, 2008, Annual Meeting of Stockholders.

#### Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference from the information contained in the sections captioned Proposal No. 2 Ratification of Selection of PricewaterhouseCoopers LLP as the Company s Independent Registered Public Accounting Firm for the Fiscal Year Ended December 31, 2008 Audit Fees and Non-Audit fees in Vermillion, Inc. s definitive Proxy Statement for the June 11, 2008, Annual Meeting of Stockholders.

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### **PART IV**

# Item 15. Exhibits, Financial Statement Schedules

- (a) The following documents are filed as part of this Annual Report on Form 10-K.
  - 1. The following consolidated financial statements of Vermillion, Inc. and subsidiaries are filed as part of this Annual Report on Form 10-K under Part II Item 8 Financial Statements and Supplementary Data:

	Page
Report of Independent Registered Public Accounting Firm	46
Consolidated Balance Sheets as of December 31, 2007 and 2006	47
Consolidated Statements of Operations for the years ended December 31, 2007 and 2006	48
Consolidated Statements of Changes in Stockholders Equity (Deficit) and Comprehensive Income (Loss) for	
the years ended December 31, 2007 and 2006	49
Consolidated Statements of Cash Flows for the years ended December 31, 2007 and 2006	50
Notes to Consolidated Financial Statements	51

2. All financial schedules have been omitted due to the required information is not applicable, or contained in the consolidated financial statements or notes thereto under Part II Item 8 Financial Statements and Supplementary Data.

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# 3. Exhibits:

# **Index to Exhibits**

Exhibit Number	Exhibit Description	Form	Incorporat	ted by Ref Exhibit	erence Filing Date	Filed Herewith
2.1	Asset Purchase Agreement by and between Invitrogen Corporation and Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) dated June 25, 2001	10-Q	000-31617	10.28	August 14, 2001	
2.2	Share Purchase Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and LumiCyte, Inc. dated May 28, 2003	8-K	000-31617	2.1	June 11, 2003	
3.1	Second Amended and Restated Certificate of Incorporation of Vermillion, Inc.	S-1	333-146354	3.1	September 27, 2007	
3.2	Amended and Restated Bylaws of Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.)	S-1/A	333-32812	3.4	August 24, 2000	
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	Indenture between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and U.S. Bank National Association dated August 22, 2003	S-3	333-109556	4.1	October 8, 2003	
4.3	Indenture between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and U.S. Bank National Association dated November 15, 2006	8-K	000-31617	4.1	November 21, 2006	
4.4	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	
4.5	Amendment to Rights Agreement between Vermillion, Inc. (formerly Ciphergen	8-K	000-31617	4.4	July 28, 2005	

Biosystems, Inc.) and Wells Fargo Bank, N.A. dated July 22, 2005

4.6 Second Amendment to Rights 8-K 000-31617 4.5 October 4, 2005 Agreement between Vermillion,

Inc. (formerly Ciphergen Biosystems, Inc.) and Wells Fargo Bank, N.A. dated September 30, 2005

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Exhibit Number	Exhibit Description	Form	Incorpora File No.	Filed Herewith		
4.7	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	Form of Preferred Stock Purchase Agreement	S-1	333-32812	10.1	March 20, 2000	
10.2	Fourth Amended and Restated Investors Rights Agreement dated March 3, 2000	S-1	333-32812	10.2	March 20, 2000	
10.3	1993 Stock Option Plan	S-1	333-32812	10.3	March 20, 2000	
10.4	Form of Stock Option	S-1/A	333-32812	10.4	August 24, 2000	
10.4	Agreement	3-1/A	333-32012	10.4	August 24, 2000	
10.5	2000 Stock Plan and related form of Stock Option Agreement	S-1/A	333-32812	10.5	August 24, 2000	
10.6	Amended and Restated 2000 Employee Stock Purchase Plan	10-Q	000-31617	10.6	November 14, 2007	
10.7	Ciphergen Biosystems, Inc. 401(k) Plan	10-K	000-31617	10.7	March 22, 2005	
10.8	Form of Warrant	S-1	333-32812	10.8	March 20, 2000	
10.9	Employment Agreement between Gail Page and Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.)	10-K	000-31617	10.39	March 17, 2006	
10.10	dated December 31, 2005 Separation Agreement and Release between Debra A. Young and Vermillion, Inc. dated November 1, 2007	8-K	000-31617	10.1	November 5, 2007	
10.11	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	
10.12	Lease Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and John Arrillaga, Trustee of the John Arrillaga Survivor s Trust and Richard T. Peery, Trustee of the Richard T. Peery Separate Property Trust, dated January 28, 2000, and Amendment No. 1 dated August 8, 2000	S-1/A	333-32812	10.12	September 27, 2000	

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10.13	Lease Agreement between Symbion and Ciphergen Biosystems A/S dated February 24, 2003	10-K	000-31617	10.37	March 31, 2003
10.14	MAS License Agreement with IllumeSys Pacific, Inc. dated April 7, 1997	S-1/A	333-32812 84	10.23	August 24, 2000

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Exhibit Number	Exhibit Description	Form	Incorpora File No.	ference Filing Date	Filed Herewith	
10.15	MAS License Agreement with Ciphergen Technologies, Inc. (formerly ISP Acquisition Corporation) dated April 7, 1997	S-1	333-32812	10.24	August 24, 2000	
10.16	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	
10.17	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	
10.18	License Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Molecular Analytical Systems, Inc. dated May 28, 2003	8-K	000-31617	99.4	June 11, 2003	
10.19	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	
10.20	Extension of Term of Service and Support Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Applied Biosystems/MDS Sciex dated March 10, 2004	10-K	000-31617	10.43	March 15, 2004	
10.21	Joint Venture Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Sumitomo	S-1	333-32812	10.25	March 20, 2000	

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Corporation

10.22 Distribution and Marketing S-1/A 333-32812 10.26 September 22, Agreement between Vermillion, 2000

Inc. (formerly Ciphergen Biosystems, Inc.) and Ciphergen Biosystems KK dated March 24,

1999

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# **Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporat File No.	Filed Herewith		
- ( - ( - ( - ( - ( - ( - ( - ( - ( - (				Exhibit	Filing Date	
10.23	First Amendment to the Joint Venture Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.), Sumitomo Corporation, SC Biosciences Corporation (a subsidiary of Sumitomo Corporation) and Ciphergen Biosystems KK dated March 15, 2002	10-K	000-31617	10.33	March 31, 2003	
10.24	Second Amendment to Joint Venture Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.), Sumitomo Corporation, SC Biosciences Corporation (a subsidiary of Sumitomo Corporation) and Ciphergen Biosystems KK dated November 15, 2002	10-K	000-31617	10.34	March 31, 2003	
10.25	Third Amendment to Joint Venture Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.), Sumitomo Corporation, SC Biosciences Corporation (a subsidiary of Sumitomo Corporation) and Ciphergen Biosystems KK dated November 15, 2002	10-K	000-31617	10.35	March 31, 2003	
10.26	Stock Purchase Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and SC Biosciences Corporation dated August 30, 2002	10-K	000-31617	10.32	March 31, 2003	
10.27	Registration Rights Agreement dated August 22, 2003, of Vermillion, Inc. s (formerly Ciphergen Biosystems, Inc.) 4.50% Convertible Senior Notes due September 1, 2008	S-3	333-109556	10.1	October 8, 2003	
10.28	Form of Exchange and Redemption Agreement dated November 3, 2006, between	8-K	000-31617	10.55	November 6, 2006	

Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and certain holders of its 4.50% Convertible Senior Notes due September 1, 2008

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Exhibit Number	Exhibit Description	Form	Incorporat File No.	ted by Ref Exhibit	erence Filing Date	Filed Herewith
10.29	Registration Rights Agreement dated November 15, 2006, between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Initial Purchasers of its 7.00% Convertible Senior Notes due September 1, 2011	8-K	000-31617	10.1	November 21, 2006	
10.30	Letter Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Oppenheimer & Co. Inc. dated August 3, 2006	S-1/A	333-146354	10.46	November 27, 2007	
10.31	Warrant with Oppenheimer & Co. Inc. dated August 3, 2006	S-1/A	333-146354	10.47	November 27, 2007	
10.32	Warrant with Oppenheimer & Co. Inc. dated November 15, 2006	S-1/A	333-146354	10.48	November 27, 2007	
10.33	Engagement Letter between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Oppenheimer & Co. Inc. dated August 3, 2006	S-1/A	333-146354	10.49	November 27, 2007	
10.34	Asset Purchase Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Pall Corporation dated October 27, 2004	8-K	000-31617	2.1	December 6, 2004	
10.35	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	
10.36	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	
10.37	Letter Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated August 29, 2007	S-1	333-146354	10.38	September 27, 2007	

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10.38	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
10.39	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
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Exhibit			Incorpora	Filed		
Number	<b>Exhibit Description</b>	Form	File No.	Exhibit	Filing Date	Herewith
10.40	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	
10.41	Credit Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.47	July 28, 2005	
10.42	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	
10.43	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	
10.44	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	
10.45	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	
10.46	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	
10.47	Amendment No. 1 to Transition Services Agreement between Vermillion, Inc. (formerly	S-1	333-146354	10.50	September 27, 2007	

Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated May 11, 2007

10.48 Amendment No. 2 to Transition S-1 333-146354 10.51 September 27, Services Agreement between 2007

Services Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated June 15, 2007

une 15, 2007

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Exhibit Number	Exhibit Description	Form	Incorporate File No.	ted by Ref Exhibit	erence Filing Date	Filed Herewith
10.49	Manufacture and Supply Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1/A	333-146354	10.56	November 27, 2007	
10.50	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	
10.51	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	
10.52	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	
10.53	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	
10.54	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	
10.55	Placement Agent Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Oppenheimer & Co. Inc. dated March 28, 2007	S-1/A	333-146354	10.61	November 27, 2007	
10.56	Securities Purchase Agreement by and among Vermillion, Inc. and the purchasers party thereto dated as of August 23, 2007	S-1	333-146354	10.57	September 27, 2007	
10.57	Form of Warrant	10-Q	000-31617	10.51	November 14, 2007	
21.0	Subsidiaries of Registrant					ü

23.1	Consent of		ü
	PricewaterhouseCoopers LLP,		
	Independent Registered Public		
	Accounting Firm		
31.1	Certification of the Chief		ü
	<b>Executive Officer Pursuant to</b>		
	Section 302 of the		
	Sarbanes-Oxley Act of 2002		
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### **Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorpora File No.	nted by Refer Exhibit	ence Filing Date	Filed Herewith
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the					ü
32.0	Sarbanes-Oxley Act of 2002 Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					(1)

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

(1) Furnished herewith.

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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 31, 2008 /s/ Gail S. Page

Gail S. PageDirector, President and Chief Executive

Officer(Principal Executive Officer)

Date: March 31, 2008 /s/ Qun Zhou

Qun ZhouCorporate Controller and Interim Chief

Financial Officer(Acting Principal Financial and

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.

Title	Date
Director, President and Chief Executive Officer (Principal Executive Officer)	March 31, 2008
,	
Corporate Controller and Interim Chief Financial Officer (Acting Principal Financial	March 31, 2008
and Accounting Officer)	
Executive Chairman	March 31, 2008
Lead Outside Director	March 31, 2008
Director	March 31, 2008
Director	March 31, 2008
	Director, President and Chief Executive Officer (Principal Executive Officer)  Corporate Controller and Interim Chief Financial Officer (Acting Principal Financial and Accounting Officer)  Executive Chairman  Lead Outside Director  Director

/s/ Michael J. Callaghan	Director	March 31, 2008
Michael J. Callaghan		
/s/ Kenneth J. Conway	Director	March 31, 2008
Kenneth J. Conway		
/s/ Rajen K. Dalal	Director	March 31, 2008
Rajen K. Dalal		

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