GENOMIC HEALTH INC
Form 10-K
March 13, 2009

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

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended: December 31, 2008

OR

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

Commission File Number: 000-51541

GENOMIC HEALTH, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**77-0552594**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
301 Penobscot Drive **Redwood City, California** *(Address of principal executive offices)*	**94063** *(Zip Code)*

(650) 556-9300
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered:**

Common Stock, par value $0.0001 per share **The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act and Title of Class:
None

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 þ

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 þ

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 þ No o

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

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 þ	Non-accelerated filer o	Smaller reporting company o
		(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 Act). Yes o No þ

As of June 30, 2008, the aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant was approximately $260.5 million, based on the closing price of the common stock as reported on the NASDAQ Global Market for that date.

There were 28,507,540 shares of the registrant s Common Stock issued and outstanding on February 28, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant s proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant s 2009 Annual Meeting of Stockholders to be held on June 8, 2009.

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PART I

ITEM 1. ***Business***.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this Report, the words expects, anticipates, intends, estimates, plans, believes, and simila expressions are intended to identify forward-looking statements. These are statements that relate to future periods and include statements about our expectation that, for the foreseeable future, substantially all of our revenues will be derived from Oncotype DX; the factors that may impact our financial results; the extent and duration of our net losses or where we may achieve profitability; our ability to recognize revenues other than on a cash basis and when we expect we will recognize a majority of revenues upon providing tests; our business strategy and our ability to achieve our strategic goals; our expectation that product revenues will increase; the amount of future revenues that we may derive from Medicare patients or categories of patients; our plans to pursue reimbursement on a case-by-case basis; our ability and expectations as to the amount of time it will take, to achieve successful reimbursement from third-party payors and government insurance programs for new tests or markets, including for Oncotype DX for N+ patients or outside of the U.S.; our expectations regarding our international expansion and opportunities, and when we may generate revenues from international sales; our intent to enter into additional foreign distribution arrangements; the factors we believe to be driving demand for Oncotype DX and our ability to sustain or increase such demand; our success in increasing patient and physician demand as a result of our direct sales approach; plans for enhancements of Oncotype DX to address different patient populations of breast cancer or to report single gene results; plans for, and the timeframe for the development or commercial launch of, future tests addressing different patient populations or other cancers; the factors that we believe will drive the establishment of coverage policies; the capacity of our clinical reference laboratory to process tests and our expectations regarding capacity; our dependence on collaborative relationships and the success of those relationships; whether any tests will result from our collaborations; the applicability of clinical results to actual outcomes; our estimates and assumptions with respect to disease incidence; our belief regarding the timing of a potential test for colon cancer; our plans with respect to potential tests for ductal carcinoma in situ, or other cancers or for patients treated with aromatase inhibitors or other treatments; the occurrence, timing, outcome or success of clinical trials or studies; our intention to plan additional development or clinical studies; the benefits of our technology platform; the economic benefits of our test to the healthcare system; the ability of our test to impact treatment decisions; our beliefs regarding our competitive benefits; our belief that multi-gene analysis provides better analytical information; our expectations regarding clinical development processes future tests may follow; our beliefs regarding the benefits of individual gene reporting; the level of investment in our sales force; our expectation that our general and administrative and sales and marketing expenses will increase and our anticipated uses of those funds; our expectations regarding capital expenditures; our expectation that our research and development expense levels will remain high as we seek to increase the clinical utility of Oncotype DX and develop new tests; our ability to comply with the requirements of being a public company; our ability to attract and retain experienced personnel; the adequacy of our product liability insurance; how we intend to spend our existing cash and cash equivalents and how long we expect our existing cash to last; our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing; our expected future sources of cash; our plans to borrow additional amounts under existing or new financing arrangements; our expectations regarding our needs to use equipment financing as a funding source; our belief that we are in material compliance with financial covenants; our expectations regarding repayment of debt or incurrence of additional debt; our compliance with federal, state and foreign regulatory requirements; the potential impact resulting from the regulation of Oncotype DX by the U.S. Food and Drug Administration, or FDA, and our belief that Oncotype DX is properly regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA; the impact of new or changing policies, regulation or legislation on our business; our belief that we have taken reasonable steps to protect our intellectual property; our strategies regarding filing additional patent applications to

strengthen our intellectual property rights; the impact of changing interest rates; our beliefs regarding our unrecognized tax benefits; the impact of accounting pronouncements and our critical accounting policies, judgments, estimates, models and assumptions on our financial results; the impact of the economy on our business, patients and payors; our expectations regarding the impact of the economic environment on our liquidity and our investments; and anticipated trends and challenges in our business and the markets in which we operate.

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Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report, as well as our ability to develop and commercialize new products; the risk of unanticipated delays in research and development efforts; the risk that we may not obtain reimbursement for our existing test and any future tests we may develop; the risks and uncertainties associated with the regulation of our test by FDA; our ability to compete against third parties; our ability to obtain capital when needed; the economic environment; and our history of operating losses. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

This report contains statistical data that we obtained from reports generated by the American Cancer Society and by DaVInci Oncology Specialists, a division of the Mattson Jackson Group, Inc., or that we derived from information contained in these reports. These reports generally indicate that they have obtained their information from sources believed to be reliable but do not guarantee the accuracy and completeness of their information. Although we believe that the reports are reliable, we have not independently verified their data.

In this report, all references to Genomic Health, we, us, or our mean Genomic Health, Inc.

Genomic Health, the Genomic Health logo, Oncotype, Oncotype DX and Recurrence Score are trademarks or registered trademarks of Genomic Health, Inc. We also refer to trademarks of other corporations and organizations in this report.

Company Overview

Genomic Health is a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests for cancer. Our goal is to improve the quality of treatment decisions for cancer patients by providing individualized information to patients and their physicians through the genomic analysis of tumor biopsies. In January 2004, we launched our first test under the brand name Onco*type* DX. Onco*type* DX has clinical evidence validating its ability to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit for early stage breast cancer patients. Onco*type* DX utilizes quantitative genomic analysis in standard tumor pathology specimens to provide tumor-specific information, or the oncotype of a tumor, in order to improve cancer treatment decisions. We offer Onco*type* DX as a clinical service, where we analyze the expression levels of 21 genes in tumor tissue samples in our laboratory and provide physicians with a quantitative gene expression profile expressed as a single quantitative score, which we call a Recurrence Score. In 2008, we began including in the Onco*type* DX report measurements of quantitative gene expression for estrogen receptor, or ER, progesterone receptor, or PR, and human epidermal growth factor receptor 2, or HER2, genes, which are used in the calculation of the Recurrence Score result, in order to provide additional clinical information.

Onco*type* DX has been extensively evaluated in twelve independent studies involving more than 4,000 breast cancer patients, including a large validation study published in *The New England Journal of Medicine* and a chemotherapy benefit study published in the *Journal of Clinical Oncology*. As of December 31, 2008, more than 85,000 tests had been delivered for use in treatment planning. As of February 2009, more than 90% of all U.S. insured lives were covered by health plans that provide reimbursement for Onco*type* DX through contracts, agreements or policy decisions. Reimbursement on behalf of patients covered by Medicare comprised 22%, 23% and 47% of product revenues for the years ended December 31, 2008, 2007 and 2006. Reimbursement on behalf of patients covered by UnitedHealthcare Insurance Company comprised 9%, 13% and 5% of product revenues for the years ended December 31, 2008, 2007 and 2006, respectively. The American Society of Clinical Oncologists, or ASCO, and the National Comprehensive Cancer Network, or NCCN, issued updated clinical practice guidelines in late 2007 that

include the use of Onco*type* DX to predict the likelihood of disease recurrence and the likelihood of chemotherapy benefit for a large portion of early stage breast cancer patients. Onco*type* DX is commercially available at a list price of $3,820 through our clinical reference laboratory located in Redwood City, California, which is accredited under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and by the College of American Pathologists, or CAP.

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Scientific Background

Limits of Existing Approaches for Determining Cancer Treatments

Cancer is a group of complex molecular diseases characterized by the uncontrolled growth and spread of abnormal cells resulting from genetic mutations or damage that can severely disrupt normal body functions. In 2008, approximately 1.4 million people in the United States and 12 million people worldwide were expected to be diagnosed with cancer. Common types of cancer include breast, prostate, lung and colon. Cancers are difficult to treat because each type responds differently, depending upon the individual and the type and location of the cancer.

To treat cancer effectively, physicians diagnose and gauge the stage of a patient s disease to determine the best course of therapy. The most common practice used to diagnose cancer is through pathologic evaluation of tumors under a microscope. For solid tumors, tumor tissue is typically removed through surgery or needle biopsy, fixed in a chemical preservative and embedded in paraffin wax. A pathologist places thin sections of this fixed paraffin embedded, or FPE, tissue onto glass slides so it can be studied under a microscope. In many cases, pathologists also use molecular staining techniques, including protein-specific staining, to improve the quality of their diagnosis. After visually examining the sample, the pathologist judges whether the biopsy contains normal or cancerous cells. The pathologist may also grade the tumor based on how aggressive the cancer cells appear under the microscope.

Once a pathologist diagnoses cancer, the patient s physician determines the stage of the cancer based on further analysis of the patient s condition using a variety of clinical measures, including the tumor pathology grade, size of the tumor, how deeply the tumor has invaded tissues at the site of origin and the extent of any invasion into surrounding organs, lymph nodes or distant sites. Patient history, physical signs, symptoms and information obtained from other tests are also evaluated and considered.

Physicians use tumor pathology grade and stage when predicting whether a cancer will recur, which is the key determinant in treatment decisions. Because tumor pathology and staging are heavily dependent on visual assessment and human interpretation, physicians and patients make treatment decisions often using subjective and qualitative information that may not reflect the molecular nature of the patient s cancer. As a result, many patients are misclassified as high risk when they are low risk for recurrence or low risk when they are high risk for recurrence, resulting in over-treatment for some and under-treatment for others.

For many cancer patients, chemotherapy is commonly used as a treatment. Chemotherapy involves the use of highly toxic drugs to kill cancer cells. It is often given after surgery to kill remaining cancer cells that could not be physically removed in order to reduce the risk of disease recurrence. Chemotherapy can take months to complete and can dramatically impact a patient s quality of life. Patients usually experience a wide range of acute toxicities, including infection, pain in the mouth and throat, weight loss, fatigue, hair loss, rashes and injection site reactions. In addition, long-term effects of chemotherapy can include cognitive impairment, cardiac tissue damage, infertility, disease of the central nervous system, chronic fatigue, secondary malignancies and personality changes. Overall benefits of chemotherapy vary significantly across cancer populations, and the benefit of treatment may not always justify the cost of the therapy or the physical and mental burden patients endure.

Use of Genomics to Understand Cancer

Genomics is the study of complex sets of genes, their expression and their function in a particular organism. A gene is a set of instructions or information that is embedded in the DNA of a cell. For a gene to be turned on or expressed by a cell, the cell must first transcribe a copy of its DNA sequence into messenger RNA, which is then translated by the cell into protein. Proteins are large molecules that control most biological processes and make up molecular pathways, which cells use to carry out their specific functions.

Genomics can also be used to understand diseases at the molecular level. Diseases can occur when mutated or defective genes inappropriately activate or block molecular pathways that are important for normal biological function. Disease can result from inheriting mutated genes or from developing mutations in otherwise normal cells. Such mutations can be the cause of cancer. The ability to detect a mutation or its functional results and to understand the process by which the mutation contributes to disease is crucial to understanding the molecular mechanisms of a disease.

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A common form of genomic analysis is the measurement of gene expression, or the presence and amount of one or more RNA sequences in a particular cell or tissue. Mutations may change the gene expression pattern of a cell as the cell responds to an altered genetic code. Quantifying the differences in gene expression has become a common way to study the behavior of an altered cell. This method allows for the measurement of the expression of single or multiple genes. These expression levels can be correlated with disease and clinical outcomes.

Advances in genomic technology have accelerated the rate and lowered the cost of gene expression analysis, thus providing unprecedented opportunity for clinical utility. We believe gene expression technology has the potential to improve the quality of diagnosis and treatment of disease by arming patients and physicians with an understanding of disease at a molecular level that is specific to each patient.

Cancer results from alterations in cells caused by the molecular changes of mutated genes. The behavior of cancer is dependent on many different genes and how they interact. Cancer is complicated and it may not be possible to identify a single gene that adequately signals a more aggressive or less aggressive type of cancer. The ability to analyze multiple genes expressed by the tumor provides more valuable information, which enables individualized cancer assessment and treatment.

The key to utilizing genomics in cancer is identifying specific sets of genes and gene interactions that are important for diagnosing different subsets of cancers. Studies can be performed which link response to therapy or the likelihood of recurrence to the pattern of gene expression in tumors. These results can then be used to develop tests that quantify gene expression of an individual s tumor, allowing physicians to better understand what treatments are most likely to work for an individual patient or how likely a cancer is to recur.

Our Solution

Our diagnostic approach correlates gene expression to clinical outcomes and provides an individualized analysis of each patient s tumor. We have optimized technology for quantitative gene expression on FPE tissue by developing methods and processes for screening hundreds of genes at a time using minimal amounts of tissue. This technology allows us to analyze archived samples of tissue, retained by hospitals for most cancer patients, to correlate gene expression analysis with known clinical outcomes, such as responsiveness to therapy or the likelihood of cancer recurrence or progression. Once we have established and validated a test, we can then analyze a patient s tumor and correlate the result to these clinical outcomes.

We believe that our multi-gene analysis, as opposed to single-gene analysis, provides a more powerful approach to distinguish tumors as being more or less likely to recur or progress. Furthermore, as shown in breast cancer, our approach can be used to determine whether a patient is more or less likely to benefit from therapy. This information ultimately allows the physician and patient to choose a course of treatment that is individualized for each patient.

Our solution fits within current clinical practice and therapeutic protocols, facilitating product adoption. We analyze tissues as they are currently handled, processed and stored by clinical pathology laboratories. Once a patient is diagnosed with breast cancer and a physician orders Onco*type* DX, the pathology lab provides us with the tumor block or thin sections from the biopsy specimen utilized for the diagnosis. Because the specimens are chemically preserved and embedded in paraffin wax, they require no special handling and can be sent by overnight mail to our clinical reference laboratory in California. We believe this provides an advantage over tests using fresh or frozen tissue that require special handling, such as shipping frozen tissue on dry ice. We typically analyze the tissue and deliver our results to the treating physician within 10 to 14 days of receipt of the tissue sample. This is within the crucial decision window after the tumor has been surgically removed and before the patient and the treating physician discuss additional treatment options.

We believe our solution provides information that has the following benefits:

Improved Quality of Treatment Decisions. We believe our approach to genomic-based cancer analysis improves the quality of cancer treatment decisions by providing an individualized analysis of each patient s tumor that is correlated to clinical outcome. Our approach represents a substantial departure from existing approaches to treatment, which often use subjective, anatomic and qualitative factors to determine treatments. Onco*type* DX has been shown in clinical studies to classify many patients into recurrence risk

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categories different from classifications based primarily on tumor pathology grade and stage. Thus, our solution enables patients and physicians to make more informed decisions about treatment risk-benefit considerations and, consequently, design an individualized treatment plan.

Improved Economics of Cancer Care. We believe that improving the quality of treatment decisions can result in significant economic benefits. In early stage breast cancer, our data shows that many patients are misclassified as high or low risk under existing treatment guidelines. Many low risk patients misclassified as high risk receive toxic and expensive chemotherapy treatment regimens. Chemotherapy and related costs may exceed $20,000, as compared to Onco*type* DX s list price of $3,820. On the other hand, some high risk patients misclassified as low risk are not provided chemotherapy treatment, possibly necessitating future treatment costing up to $50,000 or more if the cancer recurs.

Oncotype DX

Onco*type* DX, our first clinically validated product, uses our quantitative molecular pathology approach to improve cancer treatment decisions. We offer Onco*type* DX as a clinical laboratory test, where we analyze tumor tissue samples in our clinical reference laboratory and provide physicians with genomic information specific to the patient s tumor. Early stage breast cancer is the first patient population where we have commercialized a genomic test that has been shown clinically to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit.

In breast cancer, we developed our gene panel by narrowing the field of approximately 25,000 human genes down to 250 cancer-related genes through review of existing research literature and computer analysis of genomic databases. We evaluated the 250 genes in three independent clinical studies to identify a 21-gene panel whose composite gene expression profile can be represented by a single quantitative score, which we call a Recurrence Score. The higher the Recurrence Score, the more aggressive the tumor and the more likely it is to recur. The lower the Recurrence Score, the less aggressive the tumor and the less likely it is to recur. Moreover, we have demonstrated that the Recurrence Score also correlates with the likelihood of chemotherapy benefit.

Oncotype DX for Breast Cancer

In 2008, approximately 205,000 people in the United States and 1.3 million people worldwide were diagnosed with breast cancer, including ductal carcinoma in situ, or DCIS. Following diagnosis, a physician determines the stage of the breast cancer by examining the following:

the pathology of the tumor,

the size of the tumor,

node status, referred to as node positive, or N+, where the tumor has spread to the lymph nodes, and node negative, or N-, where the tumor has not spread to the lymph nodes, and

the extent to which the cancer has spread to other parts of the body.

Breast cancer tumors are classified as stage 0, I, II, III or IV. Stage 0, or DCIS, generally refers to a pre-invasive tumor with reduced risk of recurrence. DCIS is typically not treated with chemotherapy but may be treated with lumpectomy or mastectomy, followed by radiation therapy and hormonal therapy. Stage I and II are generally referred to as early stage breast cancer, and stage III and IV are generally referred to as late stage breast cancer. Standard treatment guidelines weigh the stage of the cancer and additional factors to predict cancer recurrence and determine treatment protocol such as:

the presence or absence of estrogen receptors, referred to as estrogen receptor positive, or ER+, where estrogen receptors are present, and estrogen receptor negative, or ER-, where estrogen receptors are not present,

the abundance of human epidermal growth factor receptor-type 2, or HER2, genes or protein in the tumor,

the age of the patient, and

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the histological type and grading of the tumor as reported by the pathologist.

Because these diagnostic factors have limited capability to predict future recurrence and chemotherapy benefit, and some are subjective, a large percentage of early stage breast cancer patients are classified as high risk. As a consequence, the use of chemotherapy has become standard practice in Stage I and II patients even though the benefit to this patient group as a whole is small. Most early stage breast cancer patients have N-, ER+ tumors. These patients have been demonstrated to respond well to hormonal therapy, such as tamoxifen. Identifying which of these patients will further benefit from chemotherapy is a difficult decision under these guidelines. A National Surgical Adjuvant Breast and Bowel Project, or NSABP, study published in 2004 showed that after 12 years of follow-up, overall survival in N-, ER+ breast cancer patients using tamoxifen hormonal therapy alone was approximately 83% and the overall survival using tamoxifen hormonal therapy and chemotherapy was 87%. Therefore, the incremental survival benefit of chemotherapy in this study was only 4%. Our test is designed to help identify those patients with aggressive tumors who are most likely to benefit from chemotherapy and to identify those patients with less aggressive tumors who may receive minimal clinical benefit from chemotherapy.

When the treating physician places an order for Onco*type* DX, the local pathology laboratory sends the tumor sample to our clinical reference laboratory. Once we receive the tumor sample, it is logged in and processed by our pathology department. Suitable samples then undergo a process by which RNA is extracted and purified. We then analyze the resulting material and produce a report, typically within 10 to 14 days of the receipt of the sample, that shows a Recurrence Score on a continuum between 0-100. The Recurrence Score, along with other data and tests that physicians obtain, forms the basis for the treatment decision.

The Recurrence Score has been clinically validated to correlate with an individual s likelihood of breast cancer recurrence within 10 years of diagnosis. The lower the Recurrence Score the less likely the tumor is to recur and the higher the Recurrence Score the more likely the tumor is to recur. A Recurrence Score range from 0 to 100 correlates to an actual recurrence range from about 3% recurrence to over 30% recurrence for patients in our validation study. The study involved 668 patients who were enrolled in the NSABP Study B-14 between 1982 and 1988. The continuous range of scores differentiates Onco*type* DX from other tests that predict only high or low risk by providing an individualized level of risk. To evaluate our clinical validation studies and compare Onco*type* DX to other methods of classifying risk, we defined Recurrence Score ranges for low, intermediate and high risk groups. A Recurrence Score below 18 correlates with a low likelihood of recurrence; a Recurrence Score equal to or greater than 18 but less than 31 correlates with an intermediate likelihood of recurrence; and a Recurrence Score equal to or greater than 31 correlates with a high likelihood of recurrence. Within each risk category, Onco*type* DX further quantifies the risk for any given patient. For example, a low risk patient may have as low as a 3% likelihood of recurrence of breast cancer within 10 years or as high as an 11% likelihood of recurrence, depending on the individual Recurrence Score. We believe this represents a substantial improvement upon existing methods for classifying patient risk.

Clinical Utility and Health Economic Benefits of Oncotype DX

The following table describes our current breast cancer product:

Breast Cancer Product	**Product Stage**
Onco*type* DX	
N-, ER+	Commercial
Single gene reporting (ER, PR, HER2)	Commercial
N+	Commercial

Aromatase inhibitors	Commercial

Node Negative, Estrogen Receptor Positive (N-, ER+)

In December 2007, eight studies were presented at the San Antonio Breast Cancer Symposium, or SABCS, reinforcing the clinical utility of Onco*type* DX. Three of the studies assessing the impact of Onco*type* DX on treatment decisions concluded that use of the test resulted in less recommendation for and use of chemotherapy, demonstrating the actionable nature of Onco*type* DX in its ability to help reduce unnecessary use of chemotherapy.

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In September 2008, the *Journal of Clinical Oncology* published clinical results suggesting that the Onco*type* DX Recurrence Score result provides additional prognostic information in patients with early-stage breast cancer beyond that derived from Adjuvant! Online, an online tool that evaluates clinical variables to help physicians and patients assess the risks and benefits of getting additional therapy after surgery. In October 2008, *The American Journal of Surgery* published clinical results from a study N-, ER+ patients indicating that Onco*type* DX significantly changed treatment recommendations versus standard measures alone.

Single Gene Reporting (ER, PR, HER2)

We introduced quantitative gene expression reporting for ER and PR genes with the Onco*type* DX Recurrence Score report in February 2008 and for HER2 in September 2008. We believe that reporting individual gene scores in addition to the Recurrence Score result may have additional utility in predicting outcomes for specific therapies or disease subtypes. For example, a quantitative ER score may be a clinically useful predictor of tamoxifen benefit based on our clinical studies of the NSABP Study B-14 population. In June 2008, the *Journal of Clinical Oncology* published results of a study demonstrating the utility of Onco*type* DX in measuring gene expression for ER and PR status, indicating that quantitative reverse transcription polymerase chain reaction, or RT-PCR, a well-established technology that we license, is a reliable method for determining hormone receptor status in breast cancer. At the September 2008 ASCO Breast Cancer Symposium, we presented results from two studies supporting the use of Onco*type* DX in assessing HER2 gene expression.

Node Positive (N+)

Many patients diagnosed with N+ breast cancer may not benefit from chemotherapy or may have other health issues that increase the risk of chemotherapy treatment. Results from studies of Onco*type* DX in N+ patients utilizing tumor samples from chemotherapy treated patients (anthracycline plus cytoxin or anthracycline plus taxotere), completed in collaboration with the Eastern Cooperative Oncology Group and Aventis, Inc., a member of the sanofi-aventis group, or Aventis, were presented at the June 2007 ASCO annual meeting. The results of these studies suggest that Onco*type* DX Recurrence Score results provide accurate recurrence risk information for patients with ER+ breast cancer, regardless of whether they are N- or N+. At SABCS in December 2007, we presented results from a second study conducted in conjunction with the Southwest Oncology Group suggesting that Onco*type* DX may be useful in predicting survival without disease recurrence and the benefit of chemotherapy for N+ patients, in addition to N-, ER+ patients. As a result, we have experienced an increase in usage of Onco*type* DX for N+ patients. However, substantially all of our existing reimbursement coverage is limited to women with early-stage N-, ER+ breast cancer. We may not be able to obtain reimbursement coverage for Onco*type* DX for breast cancer patients with N+, ER+ disease.

Aromatase Inhibitors

We conducted studies of Onco*type* DX with clinical samples from postmenopausal women with breast cancer who were treated with aromatase inhibitors. Aromatase inhibitors and tamoxifen are both used as standard treatment for early stage ER+ breast cancer patients. In December 2008 at SABCS, we presented results from a European study using Onco*type* DX to analyze tumor samples from over 1,200 patients in the ATAC (Arimedix®, Tamozifin, Alone or in Combination) trial, which established the wide use of aromatase inhibitors for adjuvant treatment of post-menopausal women with hormone-receptor positive breast cancer. The study demonstrated that, along with other standard measures such as tumor size, Onco*type* DX contributes independently to provide a more complete picture of prognosis for N- and N+ patients treated with aromatase inhibitors.

Health Economic Benefits

We sponsor third-party studies conducted by researchers affiliated with academic institutions to examine the health economic implications of Onco*type* DX. Two such studies, one of which was published in *The American Journal of Managed Care* in May 2005, analyzed data from patients in the NSABP Study B-14 multi-center clinical trial to compare risk classification based on guideline criteria from NCCN to risk classification by Onco*type* DX. Of the 668 patients in the NSABP study population, NCCN guidelines classified 615, or 92%, as high risk and 53, or 8%, as low risk. Of the 615 patients classified as high risk by NCCN, Onco*type* DX classified 49% as low risk, 22%

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as intermediate risk and 29% as high risk. Of the 53 patients that NCCN classified as low risk, Onco*type* DX classified 6% as high risk, 22% as intermediate risk and 72% as low risk. In each case, Onco*type* DX provided a more accurate classification of risk than the NCCN guidelines as measured by 10 year distant recurrence-free survival.

Based on these results, a model was designed to forecast quality-adjusted survival and expected costs, or the net present value of all costs of treatment until death, if Onco*type* DX was used in patients classified as low risk or high risk by NCCN guidelines. The model, when applied to a hypothetical population of 100 patients with the demographic and disease characteristics of the patients entered in the NSABP Study B-14, demonstrated an increase to quality-adjusted survival in this population of 8.6 years and a reduction in projected aggregate costs of approximately $200,000. Furthermore, the model showed that as the expected costs and anticipated toxicity of chemotherapy regimens increase, the use of the Recurrence Score to identify which patients would benefit from chemotherapy should lead to larger reductions in projected overall costs. According to this study, if all early stage breast cancer patients and their physicians used Onco*type* DX and acted on the information provided by the Recurrence Score, there would be significant economic benefit to the healthcare system.

Product Development

We developed Onco*type* DX using the following multi-phased clinical development program that we are also using to develop future products for breast, colon and other cancers:

Research phase. Prior to development, we may conduct exploratory studies to identify genes, pathways or new disease opportunities of potential scientific interest.

Early development phase. In this phase, we establish a product definition and development plan and select from the approximately 25,000 genes in the human genome to identify candidate genes. To date, we have compiled a library of over 1,300 individual cancer gene tests. Typically, we secure access to archival tumor biopsy samples correlated with clinical data in order to identify genes that correlate with a specific clinical outcome.

Development phase. If early development studies successfully identify genes, we conduct additional clinical studies to refine the gene set in the specific patient population of interest. We select the final gene panel through statistical modeling of the gene correlation data. With a gene panel established, we then finalize the remaining assay parameters.

Validation phase. Once the gene panel, assay chemistry, automation and analysis specifications are finalized, tested and verified, we begin clinical validation. In this phase, we conduct one or more validation studies with prospectively designed endpoints to test our candidate gene panel and the corresponding quantitative expression score. We are often able to conduct large validation studies using archived samples with years of clinical outcomes, thus saving clinical development time.

Commercialization and product expansion phase. Once a test is commercialized, we may perform additional studies designed to support the test s clinical utility and potentially to broaden its use in additional patient populations or for additional indications. These studies may include prospective studies to verify that our test is changing physician behavior as well as tests of a commercial product in new populations.

Product Development Opportunities in Breast Cancer

Ductal Carcinoma in Situ (DCIS)

We are investigating the utility of Onco*type* DX in patients with DCIS, which affects approximately 60,000 women per year in the United States. We plan to evaluate the use of the Onco*type* DX 21-gene panel and are also in the early development stage of identifying other existing or new genes and gene combinations that may be used for treatment planning in DCIS. In December 2008, at SABCS, we presented study results demonstrating that quantitative RT-PCR analysis is possible in DCIS that is adjacent to invasive ductal carcinoma of the breast.

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Taxane benefit test

We are in the development phase for a product to predict the likelihood of taxane benefit in breast cancer patients. Taxanes are a class of chemotherapy drugs that are used in addition to traditional chemotherapy regimens in some patients but have additional side effects and are most often used in patients with aggressive or later stage tumors.

Product Development Opportunities in Other Cancers

The following table describes our products in various stages of development for cancers other than breast cancer:

Product Opportunity	Product Stage	2008 Estimated Incidence United States	2008 Estimated Incidence Worldwide
Colon Cancer		120,000	1,200,000
Stage II	Validation		
Stage III	Early Development		
Prostate Cancer	Early Development	270,000	780,000
Renal Cancer	Early Development	40,000	210,000
Non-small Cell Lung Cancer	Early Development	160,000	1,200,000
Melanoma	Early Development	70,000	160,000

Colon Cancer

Stage II colon cancer affects approximately 30,000 to 40,000 people each year in the United States and the current treatment paradigm is unclear. About a third of patients receive adjuvant chemotherapy; however, research indicates that only 2% to 4% of patients benefit from this treatment, which has significant associated toxicity. While there are existing clinical markers associated generally with higher risk in colon cancer patients, there is no clinically validated genomic test available that predicts the likelihood of recurrence or magnitude of chemotherapy benefit for individual patients.

We have conducted studies of selected genes from four clinical studies across over 1,800 patient samples in order to identify clinically useful markers for colon cancer recurrence and response to chemotherapy. We selected a final set of genes that have been observed to be statistically significantly correlated to clinical outcome in stage II colon cancer. We are conducting an independent clinical validation study in stage II colon cancer for our 18-gene colon cancer assay, utilizing more than 1,200 patient samples from the international, multi-center QUASAR trial, which examined the benefit associated with 5-fluorouracil/leucovorin adjuvant chemotherapy. Unlike the Onco*type* DX breast cancer assay that captures both recurrence and treatment benefit in one Recurrence Score, the prognostic and predictive genes in the colon assay do not overlap. As such, our colon cancer assay was designed to generate both a prognostic Recurrence Score and a predictive Treatment Score. The clinical validation study will evaluate the association of the Recurrence Score with recurrence in stage II colon cancer patients treated with surgery alone and the association of the Treatment Score with the magnitude of chemotherapy benefit in patients treated with adjuvant chemotherapy. We anticipate reporting results of this study in the second half of 2009. If results of this study are positive, we plan to commercialize a test for colon cancer in 2010.

Other Cancers

We began gene discovery work under our collaboration agreement with Pfizer for the development of a genomic test to estimate the risk of recurrence following surgery for patients with Stage I-III renal carcinoma, clear cell type, that has not spread to other parts of the body. The clear cell type of renal carcinoma is the most common type of kidney cancer in adults. As part of the collaboration, we plan to apply the same molecular technology and clinical strategy used to develop the Onco*type* DX breast cancer test. We also established collaborations and identified sources of clinical samples in connection with our prostate and lung cancer programs.

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Product Development Opportunities for Targeted Cancer Therapeutics

Anti-cancer drugs recently approved by the U.S. Food and Drug Administration, or FDA, and new anti-cancer drugs in clinical development are designed to provide more targeted treatment, which should improve efficacy and reduce side effects. A need exists to identify those patients who, based on the genomic profile of their tumors, are most likely to benefit from these therapies. We believe genomic analysis has the potential to improve patient selection for these therapies. We have had a number of discussions with pharmaceutical companies regarding the use of Onco*type* DX or our clinical development platform to identify subsets of patients more likely to respond to a particular therapy.

EGFR inhibitor response test

We are in the development phase for tests to predict the likelihood of response to the epidermal growth factor receptor, or EGFR, inhibitor class of drugs. For example, we entered into a collaborative agreement with Bristol-Myers Squibb Company and ImClone Systems Incorporated to develop a genomic test to predict the likelihood of response to Erbitux in colorectal cancer. Erbitux is a targeted therapy currently approved for the treatment of metastatic colorectal cancer. The agreement provides for research funding support and milestone payments and provides us commercial rights to diagnostic tests that result from the collaboration. We completed early studies with Bristol-Myers Squibb and ImClone and identified a small number of genes that could predict response to Erbitux. We are planning further studies for the development of an EGFR inhibitor response test.

Targeted therapies in breast cancer

We entered into collaborative agreements with Aventis and the Eastern Cooperative Oncology Group to investigate the ability of gene expression in FPE tissues to predict the likelihood of response to adjuvant chemotherapy, including the taxane Taxotere, in patients with early breast cancer and zero to three involved lymph nodes. The agreements provide us with commercial rights to diagnostic tests that may result from the collaboration. Initial study results indicated that in patients with hormone receptor positive disease who had a Recurrence Score indicating intermediate risk of recurrence or above, a number of candidate genes strongly predicted benefit from treatment with Taxotere. A genomic classifier predicting differential benefit was identified and, if validated through additional studies, could lead to the development of a test to predict the likelihood of benefit from Taxotere.

Technology

We utilize existing technologies such as reverse transcription polymerase chain reaction, or RT-PCR, and information technologies and optimize and integrate them into new processes. We expect to continue to extend the capabilities of the various components of our process to develop effective products. Our technology allows us to:

Extract RNA from FPE-tumor Biopsies

Our product development requires that we be able to quantify the relative amounts of RNA in patients FPE tissue specimens. We have developed proprietary technology, intellectual property and know-how for optimized and automated methods for extraction and analysis of RNA from FPE tissue.

Amplify and Detect Diminished Amounts of RNA Consistently

We use RT-PCR as the basis for our quantitative molecular pathology assays. This technology uses polymerase chain reaction, or PCR along with fluorescent detection methods to quantify the relative amount of RNA in a biological specimen. We believe our technology platform has the following advantages:

Sensitivity. We have developed protocols for extracting and quantifying RNA utilizing RT-PCR. Our method for amplifying small fragmented RNA is designed to allow us in the future to conduct studies with hundreds to thousands of genes from 10 micron sections of FPE tissue. The ability to amplify RNA allows us to maintain a repository of RNA from limited tissue samples that can be used for later studies.

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Specificity. Our RT-PCR platform is highly specific because it works only when three different test reagents, called DNA probes and primers, independently match each target RNA sequence to be measured. In addition, we have designed and implemented proprietary software for selecting optimal probe and primer sequences in an automated, high-throughput process. The ability to utilize these sequences allows us to design highly specific assays for closely related sequences.

Precision and Reproducibility. The reagents, materials, instruments and controls in our processes are used by trained personnel following validated standard operating procedures. Validation studies have shown that these standard operating procedures precisely quantify tested RNA with minimal variability in the assay system across days, instruments and operators. This enables our clinical reference laboratory to produce consistently precise and accurate gene expression results. Our quality control methods for our reagents and processes, along with our software for automation, sample tracking, data quality control and statistical analysis, add to the reproducibility and precision of our test.

Dynamic Range. Because our RT-PCR platform can amplify small amounts of RNA in proportion to the amount present in the sample, we are able to measure RNA levels across as much as a hundred thousand fold range of differing RNA expression. Having a broad range of high resolution testing capability increases the quality of our correlations with clinical outcomes and therefore the predictive power of our tests.

Analyze Hundreds of Genes

The methods and know-how we have developed allow us to expand RT-PCR technology to a scale that enables screening of hundreds of genes at a time while using minimal amounts of tissue. During our initial years of operation, we typically screened 48 to 96 genes from a standard FPE tissue sample using RNA from three 10 micron sections of tissue. By 2003, we routinely screened 192 genes from each sample and, by 2004, we screened 384 genes per sample. Today, we have the capability to screen up to 768 different genes per sample without sacrificing the sensitivity, specificity and reproducibility of RT-PCR. With continued investment in miniaturization and automation, we believe that our technology will be capable of continued increases in throughput.

Employ Advanced Information Technology

We have developed computer programs to automate our RT-PCR assay process. We have also developed a laboratory information management system to track our gene-specific reagents, instruments, assay processes and the data generated. Similarly, we have automated data analysis, storage and process quality control. We use statistical methods to optimize and monitor assay performance and to analyze data from our early development and development studies.

Competition

We believe that we compete primarily on the basis of:

the value of the quantitative information Onco*type* DX provides;

the clinical validation of Onco*type* DX s ability to predict recurrence and survival, and the demonstration of Onco*type* DX s ability to predict the likelihood of chemotherapy benefit;

our ability to perform clinical studies using archival tissue as it is currently processed, handled and stored;

our ability to screen hundreds of genes at a time;

our ability to commercialize products through our clinical development platform;

our clinical collaborations with clinical study groups;

the quality of our clinical reference laboratory, which enables consistent, reproducible results;

the level of customer service we provide, both to patients and health care professionals;

the level of reimbursement coverage for Onco*type* DX;

our ability to obtain appropriate regulatory approvals in a timely fashion; and

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the inclusion of Onco*type* DX in clinical practice guidelines.

We believe that we compete favorably with respect to these factors, although we cannot assure you that we will be able to continue to do so in the future or that new products that perform better than Onco*type* DX will not be introduced. We believe that our continued success depends on our ability to:

continue to innovate and maintain scientifically advanced technology;

enhance Onco*type* DX to provide information in response to additional indications;

continue to validate our products, especially with respect to chemotherapy benefit;

continue to obtain positive reimbursement decisions from payors;

expand Onco*type* DX for use in other forms of cancer;

expand outside of the United States;

attract and retain skilled scientific and sales personnel;

obtain patents or other protection for our products and technology;

obtain and maintain our clinical reference laboratory accreditations and licenses; and

successfully market and sell Onco*type* DX.

Our principal competition comes from existing diagnostic methods used by pathologists and oncologists. These methods have been used for many years and are therefore difficult to change or supplement. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which facilitates adoption more readily than tests like Onco*type* DX that are performed outside the pathology laboratory. In addition, few diagnostic methods are as expensive as Onco*type* DX.

We also face competition from many public and private companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast cancer, such as Celera Corporation, Clarient Diagnostic Services, Agendia B.V., Applied Genomics, bioTheranostics Incorporated, Exagen and University Genomics. Commercial laboratories with strong distribution networks for diagnostic tests, such as Genzyme Corporation, Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, may become competitors. Other potential competitors include companies that develop diagnostic tests such as Bayer Diagnostics, a division of Siemens AG, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd, and Veridex LLC, a Johnson & Johnson company. Our competitors may invent and commercialize technology platforms that compete with ours. In addition, in December 2005, the federal government allocated a significant amount of funding to The Cancer Genome Atlas, a project aimed at developing a comprehensive catalog of the genetic mutations and other genomic changes that occur in cancers and maintaining the information in a free public database. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and these products may compete with ours. In addition, competitors may develop their own versions of our test in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

Our test is considered relatively expensive for a diagnostic test. We increased the price of our test from $3,650 to $3,820 effective July 1, 2008, and we may raise prices in the future. This could impact reimbursement of and demand for Onco*type* DX. Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that could be viewed by physicians and payors as functionally equivalent to our test, which could force us to lower the list price of our test and impact our operating margins and our ability to achieve profitability. Some competitors have developed tests cleared for marketing by FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than Onco*type* DX, and that could discourage adoption and reimbursement of our test. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of

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our test, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability and could cause the market price of our common stock to decline.

Commercial Operations

We believe our future success will depend in part on our ability to continue to build a strong domestic sales, marketing and reimbursement effort by interacting directly with medical and surgical oncologists, pathologists and payors. Because oncology is a concentrated specialty, we believe that a focused marketing organization and specialized sales force is necessary in order to effectively serve the oncology community. We believe our direct sales approach, targeting oncologists and breast cancer surgeons, coupled with our plans to continue to conduct multiple clinical studies with the objective of having results published in peer-reviewed journals, is the best approach to increase patient and physician demand and the number of favorable reimbursement coverage decisions by payors. In January 2009, we hired an additional 20 U.S. sales representatives, increasing our domestic sales force by 33% to a total of 80 sales representatives. All Onco*type* DX assays are processed in our clinical reference laboratory facility in Redwood City, California. For the year ended December 31, 2008, we delivered more than 39,600 test reports for use in treatment planning. As of December 2008, our clinical reference laboratory had the capacity to process up to 15,000 tests per calendar quarter. In December 2008, we launched an online physician portal with enhanced real-time delivery of patient results to physicians and the capability for placing Onco*type* DX orders online.

We believe our future success will also depend in part on our ability to continue to expand internationally. As of February 2009, we had received test samples from 40 countries and established exclusive distribution agreements for Onco*type* DX with partners in Israel, Greece, Turkey, the United Kingdom, Australia, Japan, Taiwan and Hong Kong. We have completed or initiated multiple international studies, including the ATAC study of breast cancer patients treated with aromatase inhibitors conducted by the Royal Marsden Hospital in London and the ongoing clinical validation study of our colon cancer assay using samples from the QUASAR trial, of which the majority of samples are from the United Kingdom. In September 2008, the Dutch Institute for Healthcare issued updated clinical practice guidelines that included the use of Onco*type* DX for breast cancer patients. In order to support our international efforts, we established a subsidiary in Geneva, Switzerland in February 2009 and have appointed lead executives in Europe and in Asia. We do not expect international product revenues to become a significant portion of our total revenues for at least the next three years.

Reimbursement

Revenues for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid, patients and, in some cases, from hospitals or referring laboratories who, in turn, bill third-party payors for testing. Reimbursement of Onco*type* DX by third-party payors is essential to our commercial success. In addition to the inclusion of Onco*type* DX in ASCO and NCCN breast cancer treatment guidelines, we believe the key factors that will drive broader adoption of Onco*type* DX will be acceptance by healthcare providers of its clinical benefits, demonstration of the cost-effectiveness of using our test, expanded reimbursement by third-party payors, and targeted increases in marketing and sales efforts.

Several large national commercial third-party payors, a number of regional payors, including many regional Blue Cross and Blue Shield plans, and Palmetto Government Benefits Administrators, or Palmetto GBA, the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, have issued positive coverage determinations for Onco*type* DX for patients with N-, ER+ disease. In January 2008, Medi-Cal became the first Medicaid agency to establish a policy covering our test. As of February 2009, more than 90% of all U.S. insured lives were covered by health plans that provide reimbursement for the use of Onco*type* DX for N-, ER+ patients through contracts, agreements or policy decisions.

Where policies, contracts or agreements are not in place, we pursue case-by-case reimbursement. We believe that it may take several years to achieve successful reimbursement with nearly all payors. However, we cannot predict whether, or under what circumstances, payors will reimburse for our tests. Payment amounts can also vary across individual policies and coverage and payment policies, when adopted, are generally applied prospectively

rather than retroactively. Denial of coverage by payors, or payment at inadequate levels, would have a material adverse impact on market acceptance of our tests.

Commercial Third-party Payors and Patient Pay. Where there is a payor policy, contract or agreement in place, we bill the payor, the hospital or referring laboratory as well as the patient (for deductibles and coinsurance or copayments, where applicable) in accordance with the established policy. Where there is no payor policy in place, we pursue reimbursement on behalf of each patient on a case-by-case basis. We request that physicians have a billing conversation with patients prior to a test being submitted to discuss the patient s responsibility should their policy not cover the test. We also request that the physician inform the patient that we will take on the primary responsibility for obtaining third-party reimbursement on behalf of patients, including appeals for initial denials, prior to billing a patient. With this practice established, we believe that most patients receiving the Onco*type* DX test have agreed to the test knowing that they may be responsible for all or some portion of the cost of the test should their medical insurer deny or limit coverage. Our efforts on behalf of patients take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payor denies coverage after final appeal, it may take a substantial amount of time to collect from the patient, and we may not be successful.

Medicare and Medicaid. In determining whether or not Medicare will pay for a test, the Centers for Medicare and Medicaid Services, or CMS, which oversees Medicare, can permit the contractors who process and pay Medicare claims to make that determination or it can make a national coverage determination, which will bind all Medicare contractors. To date, CMS has not issued a national coverage determination on Onco*type* DX. As a result, whether or not Medicare will cover the test when billed by us is the decision of the local Medicare carrier for California with jurisdiction to process claims submitted by us. In January 2006, National Heritage Insurance Company, or NHIC, the California Medicare contractor with responsibility for processing and paying claims submitted by us prior to September 2008, released a local coverage determination providing coverage for Onco*type* DX when used in accordance with the terms of the determination. In September 2008, responsibility for processing Medicare claims submitted by us was transitioned from NHIC to Palmetto GBA. In June 2008, Palmetto GBA adopted a local coverage determination for California that includes Onco*type* DX. This coverage decision follows identical criteria as those previously set forth by NHIC.

Under current Medicare billing rules, claims for Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be incorporated in the payment that the hospital receives for the inpatient services provided. Medicare billing rules also require hospitals to bill for the test when ordered for hospital outpatients less than 14 days following the date of the hospital procedure where the tumor tissue samples were obtained. Accordingly, we are required to bill individual hospitals for tests performed on Medicare beneficiaries during these time frames. Because we generally do not have a written agreement in place with these hospitals, we may not be paid for our tests or may have to pursue payment from the hospital on a case-by-case basis. We believe patients coming under this rule represent approximately 3% of our total testing population. We believe these billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our test, and could discourage Medicare patients from using our test. Although we are working with Medicare and other diagnostic laboratories to revise or reverse these billing rules, we have no assurance that Medicare will do so, and we also cannot ensure that hospitals will agree to arrangements to pay us for tests performed on patients falling under these rules.

In addition, each state Medicaid program, which pays for services furnished to the eligible medically indigent, will usually make its own decision whether or not to cover Onco*type* DX. In January 2008, Medi-Cal became the first Medicaid payor to establish a policy covering Onco*type* DX. We have also received a limited number of approvals from other state Medicaid programs.

We have conducted clinical studies to support the use of Onco*type* DX in patients with N+, ER+ breast cancer and have experienced an increase in usage for N+ patients. While some payors provide coverage for the use of Onco*type* DX in patients with lymph node micrometastasis (greater than 0.2mm, but not greater than 2.0 mm in size), our existing reimbursement coverage is generally limited to women with early-stage N-, ER+ breast cancer. We may not be able to obtain reimbursement coverage for Onco*type* DX for breast cancer patients who are N+, ER+ that is similar to the coverage we have obtained for early-stage N-, ER+ patients.

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The majority of our current international revenues come from two sources, patient self pay from various countries and payor reimbursement in Israel through our distribution partner. We expect international sales of Onco*type* DX to be heavily dependent on reimbursement in the future. In many countries, governments are primarily responsible for reimbursing diagnostic tests. Governments often have significant discretion in determining whether a test will be reimbursed at all, and if so, how much will be paid. Although we have agreements with distribution partners in several countries in addition to Israel, we have no direct existing contracts, agreements or policy decisions with international payors for reimbursement coverage of Onco*type* DX. We expect that it will take several years to establish coverage and reimbursement for Onco*type* DX in countries outside of the U.S.

Payment

Clinical laboratory testing services, when covered by third-party payors, are paid under various methodologies, including prospective payment systems and fee schedules. Under Medicare, payment is generally made under the Clinical Laboratory Fee Schedule with amounts assigned to specific procedure billing codes. Each Medicare carrier jurisdiction has a fee schedule that establishes the price for each specific laboratory billing code. The Social Security Act establishes that these fee schedule amounts are to be increased annually, subject to certain limitations, by the percentage increase in the consumer price index, or CPI, for the prior year. Congress has frequently legislated that the CPI increase not be implemented. In the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA, Congress eliminated the CPI update through 2008. In addition, the National Limitation Amount, or NLA, which acts as a ceiling on Medicare reimbursement, is set at a percentage of the median of all the carrier fee schedule amounts for each test code. In the past, Congress has frequently lowered the percentage of the median used to calculate the NLA in order to achieve budget savings. Currently, the NLA ceiling is set at 74% of the medians for established tests and 100% of the median for diagnostic tests for which no limitation amount was established prior to 2001. Thus, no Medicare carrier can pay more than the NLA amount for any specific code.

There is no specific Current Procedural Terminology, or CPT, procedure code or group of codes to report Onco*type* DX. Therefore, the test generally must be reported under a non-specific, unlisted procedure code, which is subject to manual review of each claim. We were informed by NHIC that, under the local coverage determination, claims are to be paid consistent with the average allowed reimbursement rate for Onco*type* DX claims that were billed and processed to completion as of September 30, 2005. This rate remains in effect at the date of this report.

A Healthcare Common Procedure Coding System, or HCPCS code has been issued effective January 1, 2006 that some private third-party payors may accept on claims for the Onco*type* DX test. Medicare will not accept this HCPCS code, however. In the future, we may move forward with plans to obtain specific CPT procedure coding. If we do move forward with plans to obtain specific CPT coding, there is no assurance that specific coding will be adopted. Whether or not we obtain a specific CPT code for the test, there can be no assurance that an adequate payment rate will continue to be assigned to the test.

On several occasions, including in 2003 during the negotiations over the MMA, Congress has considered imposing a 20% co-insurance amount on clinical laboratory services, which would require beneficiaries to pay a portion of the cost of their clinical laboratory testing. Although that requirement has not been enacted at this time, Congress could decide to impose such an obligation at some point in the future. If so, it could make it more difficult for us to collect co-insurance payments for Onco*type* DX.

Regulation

Clinical Laboratory Improvement Amendments of 1988

As a clinical reference laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under CLIA, we are required to hold a certificate applicable to the type of work we perform and to comply with standards covering personnel, facilities administration, quality systems and proficiency testing.

We have a certificate of accreditation under CLIA to perform testing and are accredited by CAP. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. The standards applicable to the testing which we perform may change over time. We cannot assure you

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that we will be able to operate profitably should regulatory compliance requirements become substantially more costly in the future.

If our clinical reference laboratory is out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for services provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanction, our business could be harmed.

U.S. Food and Drug Administration

FDA regulates the sale or distribution through interstate commerce of medical devices, including in vitro diagnostic test kits. Devices subject to FDA regulation must undergo pre-market review prior to commercialization unless the device is of a type exempted from such review. In addition, manufacturers of medical devices must comply with various regulatory requirements under the Federal Food, Drug and Cosmetic Act and regulations promulgated under that Act, including quality system review regulations, unless exempted from those requirements for particular types of devices. Entities that fail to comply with FDA requirements can be liable for criminal or civil penalties, such as recalls, detentions, orders to cease manufacturing and restrictions on labeling and promotion.

Clinical laboratory tests like Onco*type* DX are regulated under CLIA, as administered by CMS, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called laboratory developed tests, or LDTs. Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We believe that Onco*type* DX is not a diagnostic kit and also believe that it is an LDT. As a result, we believe Onco*type* DX should not be subject to regulation under established FDA policies. The container we provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be considered a medical device subject to FDA regulation but is currently exempt from pre-market review by FDA.

In January 2006, we received a letter from FDA regarding Onco*type* DX inviting us to meet with FDA to discuss the nature and appropriate regulatory status of and the least burdensome ways that we may fulfill any FDA pre-market review requirements that may apply. In September 2006, FDA issued draft guidance on a new class of tests called In Vitro Diagnostic Multivariate Index Assays , or IVDMIAs. Under this draft guidance, Onco*type* DX could be classified as either a Class II or a Class III medical device, which may require varying levels of FDA pre- market review depending upon intended use and on the level of control necessary to assure the safety and effectiveness of the test. In July 2007, FDA posted revised draft guidance that addressed some of the comments submitted in response to the September 2006 draft guidance. The revised draft guidance includes an 18 month transition period of FDA enforcement discretion following release of final guidance for currently available tests if the laboratory submits a pre-market review submission within 12 months of the publication of final guidance. The comment period for this revised guidance expired in October 2007.

In May 2007, FDA issued a guidance document Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis. This guidance document was developed to support the classification of gene expression profiling test systems for breast cancer prognosis into Class II. In addition, in June 2007, FDA issued a guidance document Pharmacogenetic Tests and Genetic Tests for Heritable Markers which provides recommendations to sponsors and FDA reviewers in preparing and reviewing pre-market approval applications, or PMA, and pre-market notification, or 510(k), submissions for pharmacogenetic and other human genetic tests, whether testing is for single markers or for multiple markers simultaneously (multiplex tests).

In addition, the Secretary of the Department of Health and Human Services, or HHS, requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report s recommendations for increased oversight of genetic testing were to result in further regulatory burdens it could have a negative impact on our business and could delay the commercialization of tests in development.

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We are continuing our ongoing dialogue with FDA and HHS regarding the Onco*type* DX breast cancer assay. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for Onco*type* DX, either through new enforcement policies adopted by FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law and may result in increased regulatory burdens for us to continue to offer the Onco*type* DX assay.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained, and FDA could require that we stop selling our test pending pre-market clearance or approval. If our test is allowed to remain on the market but there is uncertainty about our test, if it is labeled investigational by FDA, or if labeling claims FDA allows us to make are limited, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a PMA application with FDA. If pre-market review is required by FDA, there can be no assurance that our test will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of Onco*type* DX if we determine that doing so would be appropriate.

Should any of the reagents obtained by us from vendors and used in conducting our test be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

Health Insurance Portability and Accountability Act

Under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, HHS has issued regulations to protect the privacy and security of protected health information used or disclosed by health care providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

We developed policies and procedures to comply with these regulations by the respective compliance enforcement dates. The requirements under these regulations may change periodically and could have an effect on our business operations if compliance becomes substantially more costly than under current requirements.

In addition to federal privacy regulations, there are a number of state laws governing confidentiality of health information that are applicable to our operations. New laws governing privacy may be adopted in the future as well. We have taken steps to comply with health information privacy requirements to which we are aware that we are subject. However, we can provide no assurance that we are or will remain in compliance with diverse privacy requirements in all of the jurisdictions in which we do business. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse impact on our business.

Federal and State Physician Self-referral Prohibitions

We are subject to the federal physician self-referral prohibitions commonly known as the Stark Law, and to similar restrictions under California s Physician Ownership and Referral Act, commonly known as PORA. Together these restrictions generally prohibit us from billing a patient or any governmental or private payor for any test when the physician ordering the test, or any member of such physician s immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Both the Stark Law and PORA contain an exception for referrals made by physicians who hold investment interests in a publicly traded company that has stockholders equity exceeding $75 million at the end of its most recent fiscal year or on average during the previous three fiscal years, and which satisfies certain other requirements. In addition, both the Stark Law and PORA contain an exception for compensation paid to a physician for personal services rendered by the physician. We have compensation arrangements with a number of physicians for personal services, such as speaking engagements and specimen tissue preparation. We have structured these arrangements with terms intended to comply with the requirements of the personal services exception to Stark and PORA.

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However, we can not be certain that regulators would find these arrangements to be in compliance with Stark, PORA or similar state laws. We would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payor or the Medicare program, as applicable.

Sanctions for a violation of the Stark Law include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $15,000 for each service arising out of the prohibited referral;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law s prohibition.

These prohibitions apply regardless of the reasons for the financial relationship and the referral. No finding of intent to violate the Stark Law is required for a violation. In addition, under an emerging legal theory, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act.

Further, a violation of PORA is a misdemeanor and could result in civil penalties and criminal fines. Finally, other states have self-referral restrictions with which we have to comply that differ from those imposed by federal and California law. While we have attempted to comply with the Stark Law, PORA and similar laws of other states, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide an assurance that we will be found to be in compliance with these laws following any such regulatory review.

Federal and State Anti-kickback Laws

The Federal Anti-kickback Law makes it a felony for a provider or supplier, including a laboratory, to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal health care program. A violation of the Anti-kickback Law may result in imprisonment for up to five years and fines of up to $250,000 in the case of individuals and $500,000 in the case of organizations. Convictions under the Anti-kickback Law result in mandatory exclusion from federal health care programs for a minimum of five years. In addition, HHS has the authority to impose civil assessments and fines and to exclude health care providers and others engaged in prohibited activities from Medicare, Medicaid and other federal health care programs.

Actions which violate the Anti-kickback Law or similar laws may also involve liability under the Federal False Claims Act, which prohibits the knowing presentation of a false, fictitious or fraudulent claim for payment to the U.S. Government. Actions under the Federal False Claims Act may be brought by the Department of Justice or by a private individual in the name of the government.

Although the Anti-kickback Law applies only to federal health care programs, a number of states, including California, have passed statutes substantially similar to the Anti-kickback Law pursuant to which similar types of prohibitions are made applicable to all other health plans and third-party payors. Both California s fee-splitting statute, Business and Professions Section 650, and its Medi-Cal anti-kickback statute, Welfare and Institutions Code Section 14107.2, have been interpreted by the California Attorney General and California courts in substantially the

same way as HHS and the courts have interpreted the Anti-kickback Law. A violation of Section 650 is punishable by imprisonment and fines of up to $50,000. A violation of Section 14107.2 is punishable by imprisonment and fines of up to $10,000.

Federal and state law enforcement authorities scrutinize arrangements between health care providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals and opportunities. The law enforcement authorities, the courts and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between health care providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of

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the scope of the Anti-kickback Law, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce future referrals.

In addition to statutory exceptions to the Anti-kickback Law, regulations provide for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-kickback Law. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection. There are no regulatory safe harbors to California s Section 650.

Among the safe harbors that may be relevant to us is the discount safe harbor. The discount safe harbor potentially applies to discounts provided by providers and suppliers, including laboratories, to physicians or institutions where the physician or institution bills the payor for the test, not when the laboratory bills the payor directly. If the terms of the discount safe harbor are met, the discounts will not be considered prohibited remuneration under the Anti-kickback Law. This safe harbor may therefore be potentially applicable to our agreements to sell tests to hospitals where the hospital submits a claim to the payor.

California does not have a discount safe harbor. However, as noted above, Section 650 has generally been interpreted consistent with the Anti-kickback Law.

The personal services safe harbor to the Anti-kickback Law provides that remuneration paid to a referral source for personal services will not violate the Anti-kickback Law provided all of the elements of that safe harbor are met. One element is that, if the agreement is intended to provide for the services of the physician on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals. Our personal services arrangements with some physicians did not meet the specific requirement of this safe harbor that the agreement specify exactly the schedule of the intervals of time to be spent on the services because the nature of the services, such as speaking engagements, does not lend itself to exact scheduling and therefore meeting this element of the personal services safe harbor is impractical. Failure to meet the terms of the safe harbor does not render an arrangement illegal. Rather, such arrangements must be evaluated under the language of the statute, taking into account all facts and circumstances.

While we believe that we are in compliance with the Anti-kickback Law and Section 650, there can be no assurance that our relationships with physicians, hospitals and other customers will not be subject to investigation or a successful challenge under such laws. If imposed for any reason, sanctions under the Anti-kickback Law and Section 650 could have a negative effect on our business.

Other Federal and State Fraud and Abuse Laws

In addition to the requirements that are discussed above, there are several other health care fraud and abuse laws that could have an impact on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal health care programs substantially in excess of its usual charges for its services. The terms usual charge and substantially in excess are ambiguous and subject to varying interpretations.

Further, the Federal False Claims Act prohibits a person from knowingly submitting a claim or making a false record or statement in order to secure payment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government s involvement, then the plaintiff

will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid programs. California has an analogous state false claims act applicable to all payors, as do many other states.

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California Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our clinical reference laboratory under California law. Such laws establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

If our clinical reference laboratory is out of compliance with California standards, the California Department of Health Services, or DHS, may suspend, restrict or revoke our license to operate our clinical reference laboratory, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain a current license in good standing with DHS. However, we cannot provide assurance that DHS will at all times in the future find us to be in compliance with all such laws.

New York Laboratory Licensing

Because we receive specimens from New York State, our clinical reference laboratory is required to be licensed by New York. We maintain such licensure for our clinical reference laboratory under New York state laws and regulations, which establish standards for:

day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel;

physical requirements of a facility;

equipment; and

quality control.

New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York State Department of Health, or DOH, may suspend, limit, revoke or annul the laboratory s New York license, censure us as the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory s being found guilty of a misdemeanor under New York law. Should we be found out of compliance with New York laboratory requirements, we could be subject to such sanctions, which could harm our business. We maintain a current license in good standing with DOH. However, we cannot provide assurance that DOH will at all times find us to be in compliance with all such laws.

Other States Laboratory Testing

Florida, Maryland, Pennsylvania and Rhode Island require out-of-state laboratories which accept specimens from those states to be licensed. We have obtained licenses in those four states and believe we are in compliance with applicable licensing laws.

From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

Environmental Laws

We are subject to regulation under federal, state and local laws and regulations governing environmental protection and the use, storage, handling and disposal of hazardous substances. The cost of complying with these laws and regulations may be significant. Our activities currently require the controlled use of potentially harmful biological materials, hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of

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contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have.

Regulation Outside of the United States

For marketing outside the United States, we are subject to foreign regulatory requirements governing human clinical testing and marketing approval for our products. These requirements vary by jurisdiction, differ from those in the United States and may require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Patents and Proprietary Technology

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. To that end, we rely on a combination of patents, patent applications, copyrights and trademarks, as well as contracts, such as confidentiality, material data transfer, license and invention assignment agreements. We also rely upon trade secret laws to protect some improvements, know-how and continuing technological .innovation. In addition, we have what we consider to be reasonable security measures in place to maintain confidentiality. Our intellectual property strategy is intended to develop and maintain our competitive position.

As of December 31, 2008, we had two issued patents in the U.S., one of which was issued jointly to us and to NSABP, and a number of pending U.S. patent applications, including provisional and non-provisional filings. Our issued patents expire in 2023 and 2024, respectively. Some of these U.S. patent applications also have corresponding pending or granted applications under the Patent Cooperation Treaty in Canada, Europe, Japan, Australia and other jurisdictions. In these patent applications, we have either sole or joint ownership positions. In those cases where joint ownership positions were created, we have negotiated contractual provisions providing us with the opportunity to acquire exclusive rights under the patent applications. Under three patent applications, we have elected to allow exclusive options to lapse without exercising the option. The joint ownership agreements generally are in the form of material data transfer agreements that were executed at the onset of our collaborations with third parties.

Our patent applications relate to two main areas: gene expression technology methods, and gene markers for cancer recurrence and drug response in certain forms of cancer. We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights. Our patent applications may not result in issued patents, and we cannot assure you that any patents that might issue will protect our technology. Any patents issued to us in the future may be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that is not covered by our patents. We cannot be certain that the steps we have taken will prevent the misappropriation of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

We have received notices of claims of infringement, misappropriation or misuse of other parties proprietary rights in the past and may from time to time receive additional notices. Some of these claims may lead to litigation. We cannot assure you that we will prevail in these actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or the validity of patents issued to us in the future, will not be asserted or prosecuted against us, or that any assertions of misappropriation, infringement or misuse or prosecutions seeking to establish the validity of our patents will not materially or adversely affect our business, financial condition and results of operations.

An adverse determination in litigation or interference proceedings to which we may become a party relating to any patents issued to us in the future or any patents owned by third parties could subject us to significant liabilities to third parties or require us to seek licenses from third parties. Furthermore, if we are found to willfully infringe these

patents, we could, in addition to other penalties, be required to pay treble damages. Although patent and intellectual property disputes in this area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory or commercially feasible terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign Onco*type* DX or other of our tests to avoid infringement, or such redesign may take considerable time, and force us to reassess our business plans. Adverse determinations in a judicial or administrative

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proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling Onco*type* DX or other of our tests, which would have a significant adverse impact on our business.

All employees and technical consultants working for us are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. Confidentiality agreements provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. In addition, agreements with employees provide that all inventions conceived by the individual while employed by us are our exclusive property. We cannot provide any assurance that employees and consultants will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our technology or obtain and use information that we regard as proprietary.

Roche License Agreement

We license from Roche Molecular Systems, Inc., on a non-exclusive basis, a number of U.S. patents claiming nucleic acid amplification processes known as polymerase chain reaction, or PCR, homogeneous polymerase chain reaction, and RT-PCR. We use these processes in our research and development and in the processing of our tests. The Roche license is limited to the performance of clinical laboratory services within the United States and Puerto Rico, and does not include the right to make or sell products using the patented processes. The license continues as long as the underlying patent rights are in effect, but is subject to early termination by Roche under the following circumstances:

a change in our ownership;

a declaration of bankruptcy or insolvency, the making of an assignment for the benefit of our creditors, having a receiver appointed, or losing the federal or state licenses necessary for our operation;

a change in our status to a non-profit entity or government institution; or

our breach of or default under a material term of the license.

If the Roche license is terminated, we will be unable to use the licensed processes to conduct research and development or to perform our tests. As payment for the licenses granted to us, we make royalty payments to Roche consisting of a specified percentage of our net revenues.

Research and Development Expenses

Research and development expenses were $28.6 million, $22.1 million and $12.8 million for the years ended December 31, 2008, 2007 and 2006, respectively. During 2008, we continued to conduct research and development studies in breast cancer, colon cancer and other cancers. We began gene discovery work under our collaboration agreement for the development of a genomic test to estimate the risk of recurrence following surgery for patients with Stage I-III renal carcinoma, clear cell type. We also established collaborations and identified sources of clinical samples in connection with our prostate and lung cancer programs.

Employees

As of December 31, 2008, we had 387 employees, including 72 in clinical reference laboratory operations, 109 in research and development, 117 in sales and marketing, 49 in information technology, including bioinformatics, and 40 in general and administrative functions, including finance, human resources and facilities. None of our employees are covered by collective bargaining arrangements, and our management considers its relationships with employees to be

good.

Available Information

We were incorporated in Delaware in August 2000, and our website is located at *www.genomichealth.com.* We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission. Our website and the

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information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

ITEM 1A. ***Risk Factors***.

We are an early stage company with a history of net losses, and we expect to incur net losses for the foreseeable future.

We have incurred substantial net losses since our inception. For the year ended December 31, 2008, we incurred net losses of $16.1 million. From our inception in August 2000 through December 31, 2008, we had an accumulated deficit of $168.5 million. To date, we have not, and we may never, achieve revenues sufficient to offset expenses. We expect to devote substantially all of our resources to continue to invest in our product pipeline, including Onco*type* DX and future products, and our commercial and laboratory infrastructure.

We expect to incur additional losses in the future and we may never achieve profitability.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to achieve profitability.

In recent years, we have incurred significant costs in connection with the development of Onco*type* DX. Our research and development expenses were $28.6 million for the year ended December 31, 2008. We expect our research and development expense levels to remain high and to continue to increase for the foreseeable future as we seek to expand the clinical utility of our existing test and develop new tests. As a result, we will need to generate significant revenues in order to achieve profitability. Our failure to achieve profitability in the future could cause the market price of our common stock to decline.

Declining general economic or business conditions may have a negative impact on our business.

Concerns over inflation, deflation, energy costs, geopolitical issues, the availability and cost of credit, the Federal stimulus package, Federal budget proposals, the U.S. mortgage market and a declining real estate market in the U.S. have contributed to increased volatility and diminished expectations for the global economy and expectations of slower global economic growth going forward. These factors, combined with volatile oil prices, declining business and consumer confidence, a declining stock market and increased unemployment, have precipitated an economic slowdown and recession. If the economic climate in the U.S. does not improve or continues to deteriorate, our business, including our patient population, our suppliers and our third-party payors, could be negatively affected, resulting in a negative impact on our product revenues.

If third-party payors, including managed care organizations and Medicare, do not provide reimbursement or rescind their favorable reimbursement policies for Oncotype DX, its commercial success could be compromised.

Physicians and patients may decide not to order Onco*type* DX unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid, pay a substantial portion of the test price. Reimbursement by a third-party payor may depend on a number of factors, including a payor s determination that tests using our technologies are:

not experimental or investigational,

medically necessary,

appropriate for the specific patient,

cost-effective,

supported by peer-reviewed publications, and

included in clinical practice guidelines.

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There is uncertainty concerning third-party payor reimbursement of any test, including Onco*type* DX. Several entities conduct technology assessments of medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. Although there are a number of favorable assessments of Onco*type* DX, the test has received negative assessments in the past and may receive additional negative assessments in the future.

Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals is a time-consuming and costly process. To date, we have secured policy-level reimbursement approval from a number of third-party payors. We cannot be certain that coverage for Onco*type* DX will be provided in the future by additional third-party payors or that existing reimbursement policies will remain in place.

Under current Medicare billing rules, claims for Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be incorporated in the payment that the hospital receives for the inpatient services provided. Medicare billing rules also require hospitals to bill for the test when ordered for hospital outpatients less than 14 days following the date of the hospital procedure where the tumor tissue samples were obtained. Accordingly, we are required to bill individual hospitals for tests performed on Medicare beneficiaries during these time frames. Because we generally do not have a written agreement in place with these hospitals, we may not be paid for our tests or may have to pursue payment from the hospital on a case-by-case basis. We believe patients coming under this rule represent approximately 3% of our total testing population. We believe these billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our test, and could discourage Medicare patients from using our test. Although we are working with Medicare and other diagnostic laboratories to revise or reverse these billing rules, we have no assurance that Medicare will do so, and we also cannot ensure that hospitals will agree to arrangements to pay us for tests performed on patients falling under these rules.

Insurers, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of health care services. From time to time, Congress has considered and implemented changes in the Medicare fee schedules in conjunction with budgetary legislation. Further reductions of reimbursement for Medicare services may be implemented from time to time. Reductions in the reimbursement rates of other third-party payors have occurred and may occur in the future. These measures have resulted in reduced payment rates and decreased test utilization for the clinical laboratory industry.

Following reporting of clinical studies to support the use of Onco*type* DX in patients with N+, ER+ breast cancer, we experienced an increase in usage for N+ patients. While some payors provide coverage for the use of Onco*type* DX in patients with lymph node micrometastasis (less than 2mm in size), our existing reimbursement coverage is generally limited to women with early-stage N-, ER+ breast cancer. We may not be able to obtain reimbursement coverage for Onco*type* DX for breast cancer patients who are N+, ER+ that is similar to the coverage we have obtained for early-stage N-, ER+ patients. In addition, we may not be able to obtain reimbursement coverage for any other new test or test enhancement we may develop in the future.

If we are unable to obtain reimbursement approval from private payors and Medicare and Medicaid programs for Onco*type* DX, or if the amount reimbursed is inadequate, our ability to generate revenues from Onco*type* DX could be limited. Even if we are being reimbursed, insurers may withdraw their coverage policies or cancel their contracts with us at any time, stop paying for our test or reduce the payment rate for our test, which would reduce our revenue.

We depend on a limited number of payors for a significant portion of our product revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our test, our revenues could

decline.

For the years ended December 31, 2008 and 2007, one payor, Medicare, as administered by NHIC and Palmetto GBA, accounted for 22% and 23% of our product revenues, respectively. Another payor, United HealthCare Insurance Company, accounted for 9% and 13% of our product revenues for the years ended December 31, 2008 and 2007, respectively. NHIC was the local Medicare carrier for California with jurisdiction

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for claims submitted by us for Medicare patients in the United States prior to September 2008, when responsibility for processing Medicare claims submitted by us was transitioned from NHIC to Palmetto GBA. In the future, it is possible that Palmetto GBA or other third-party payors that provide reimbursement for our test may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such actions could have a negative impact on our revenues.

If FDA were to begin regulating our test, we could be forced to stop sales of Oncotype DX, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for or reimbursement of our test.

Clinical laboratory tests like Onco*type* DX are regulated under CLIA, as administered through CMS, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called laboratory developed tests, or LDTs. Most LDTs are not currently subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We believe that Onco*type* DX is not a diagnostic kit and also believe that it is an LDT. As a result, we believe Onco*type* DX should not be subject to regulation under established FDA policies. The container we provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA regulation but is currently exempt from pre-market review by FDA.

In January 2006, we received a letter from FDA regarding Onco*type* DX inviting us to meet with FDA to discuss the nature and appropriate regulatory status of and the least burdensome ways that we may fulfill any FDA pre-market review requirements that may apply. In September 2006, FDA issued draft guidance on a new class of tests called In Vitro Diagnostic Multivariate Index Assays , or IVDMIAs. Under this draft guidance, Onco*type* DX could be classified as either a Class II or a Class III medical device, which may require varying levels of FDA pre-market review depending upon intended use and on the level of control necessary to assure the safety and effectiveness of the test. In July 2007, FDA posted revised draft guidance that addressed some of the comments submitted in response to the September 2006 draft guidance. The revised draft guidance includes an 18 month transition period of FDA enforcement discretion following release of final guidance for currently marketed tests if the laboratory submits a pre-market review submission within 12 months of the publication of final guidance. The comment period for this revised guidance expired in October 2007.

In May 2007, FDA issued a guidance document Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis. This guidance document was developed to support the classification of gene expression profiling test systems for breast cancer prognosis into Class II. In addition, in June 2007, FDA issued a guidance document Pharmacogenetic Tests and Genetic Tests for Heritable Markers which provides recommendations to sponsors and FDA reviewers in preparing and reviewing pre-market approval applications, or PMA, and pre-market notification, or 510(k), submissions for pharmacogenetic and other human genetic tests, whether testing is for single markers or for multiple markers simultaneously (multiplex tests).

In addition, the Secretary of the Department of Health and Human Services, or HHS, requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report s recommendations for increased oversight of genetic testing were to result in further regulatory burdens it could have a negative impact on our business and could delay the commercialization of tests in development.

We are continuing our ongoing dialogue with FDA and HHS regarding the Onco*type* DX breast cancer assay. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for Onco*type* DX, either through new enforcement policies adopted by FDA or new legislation enacted by Congress. It is

possible that legislation will be enacted into law and may result in increased regulatory burdens for us to continue to offer the Onco*type* DX assay.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained, and FDA could require that we stop selling our test pending pre-market clearance or approval. If our test is allowed to remain on the market but there is uncertainty about our test, if it is labeled investigational by FDA, or if labeling claims FDA allows us to make are very limited, orders or

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reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a PMA application with FDA. If pre-market review is required by FDA, there can be no assurance that our test will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of Onco*type* DX if we determine that doing so would be appropriate.

Should any of the reagents obtained by us from vendors and used in conducting our test be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

If we were required to conduct additional clinical trials prior to continuing to sell Oncotype DX or marketing any new test, those trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to become profitable.

If FDA decides to regulate our tests, it may require additional pre-market clinical testing prior to submitting a regulatory application for commercial sales. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our test. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our test, or to become profitable.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. 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, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform testing. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. Moreover, several states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our test.

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If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to sell Onco*type* DX, which would limit our revenues and harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states.

We are subject to other regulation by both the federal government and the states in which we conduct our business, including:

- Medicare billing and payment regulations applicable to clinical laboratories;
- the federal Medicare and Medicaid Anti-kickback Law and state anti-kickback prohibitions;
- the federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;
- the federal Health Insurance Portability and Accountability Act of 1996;
- the Medicare civil money penalty and exclusion requirements; and
- the federal civil and criminal False Claims Act and state equivalents.

We have adopted policies and procedures designed to comply with these laws, including policies and procedures relating to financial arrangements between us and physicians who refer patients to us. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and sales organization may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Our financial results depend on sales of one test, Oncotype DX, and we will need to generate sufficient revenues from this and other tests to run our business.

For the foreseeable future, we expect to derive substantially all of our revenues from sales of one test, Onco*type* DX. We have been selling this test since January 2004. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing test. We do not currently expect to commercialize a test for colon cancer until 2010, and there can be no assurance that we will be successful in doing so. We are not currently able to estimate when we may be able to commercialize tests for other cancers or whether we will be successful in doing so. If we are unable to increase sales of Onco*type* DX or to successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve profitability would be impaired, and the market price of our common stock could decline.

New test development involves a lengthy and complex process, and we may be unable to commercialize any of the tests we are currently developing.

We have multiple tests in various stages of development and devote considerable resources to research and development. For example, we are currently in the validation phase of the application of our technology to predict recurrence and the therapeutic benefit of chemotherapy in colon cancer, and we are conducting research or early development studies in prostate, renal cell and lung cancers and melanoma. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of other types of cancer, such as colon cancer, with the sensitivity and specificity necessary to be clinically and commercially useful, or that our colon cancer assay will

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succeed in meeting one or more clinical endpoints. In addition, before we can develop diagnostic tests for new cancers and commercialize any new products, we will need to:

conduct substantial research and development;

conduct validation studies;

expend significant funds; and

develop and scale our laboratory processes to accommodate different tests.

The product development process involves a high degree of risk and takes several years. Our product development efforts may fail for many reasons, including:

failure of the product at the research or development stage;

difficulty in accessing archival tissue samples, especially tissue samples with known clinical results; or

lack of clinical validation data to support the effectiveness of the product.

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop products, we will have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

If we are unable to support demand for our tests, our business may suffer.

We have added a second shift at our clinical reference laboratory facility and will need to ramp up our testing capacity as our test volume grows. We will need to continue to implement increases in scale and related processing, customer service, billing and systems process improvements, and to expand our internal quality assurance program to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As additional products are commercialized, we will need to bring new equipment on-line, implement new systems, controls and procedures and hire personnel with different qualifications. Failure to implement necessary procedures or to hire the necessary personnel could result in higher cost of processing or an inability to meet market demand. There can be no assurance that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of test results, or that we will be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for Onco*type* DX or future products, our reputation could be harmed and our future prospects and our business could suffer.

We may experience limits on our revenues if physicians decide not to order our test.

If medical practitioners do not order Onco*type* DX or any future tests developed by us, we will likely not be able to create demand for our products in sufficient volume for us to become profitable. To generate demand, we will need to

continue to make oncologists, surgeons and pathologists aware of the benefits of Onco*type* DX and any products we may develop in the future through published papers, presentations at scientific conferences and one-on-one education by our sales force. In addition, we will need to demonstrate our ability to obtain adequate reimbursement coverage from third-party payors.

Prior to the inclusion of Onco*type* DX in clinical guidelines, guidelines and practices regarding the treatment of breast cancer often recommended that chemotherapy be considered in most cases, including many cases in which our test might indicate that, based on our clinical trial results, chemotherapy would be of little or no benefit. Accordingly, physicians may be reluctant to order a test that may suggest recommending against chemotherapy in treating breast cancer. Moreover, our test provides quantitative information not currently provided by pathologists

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and it is performed at our facility rather than by the pathologist in a local laboratory, so pathologists may be reluctant to support our test. These facts may make it difficult for us to convince medical practitioners to order Onco*type* DX for their patients, which could limit our ability to generate revenues and our ability to achieve profitability.

We may experience limits on our revenues if patients decide not to use our test.

Some patients may decide not to use our test due to its price, part or all of which may be payable directly by the patient if the applicable payor denies reimbursement in full or in part. Even if medical practitioners recommend that their patients use our test, patients may still decide not to use Onco*type* DX, either because they do not want to be made aware of the likelihood of recurrence or they wish to pursue a particular course of therapy regardless of test results. Additionally, the current economic slowdown could negatively impact patients, resulting in loss of healthcare coverage, delayed medical checkups or inability to pay for a relatively expensive test. If only a small portion of the patient population decides to use our test, we will experience limits on our revenues and our ability to achieve profitability.

If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position would be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. For example, technologies in addition to ours now reportedly permit measurement of gene expression in fixed paraffin embedded, or FPE, tissue specimens. New chemotherapeutic or biologic strategies are being developed that may increase survival time and reduce toxic side effects. These advances require us to continuously develop new products and enhance existing products to keep pace with evolving standards of care. Our test could become obsolete unless we continually innovate and expand our product to demonstrate recurrence and treatment benefit in patients treated with new therapies. New treatment therapies typically have only a few years of clinical data associated with them, which limits our ability to perform clinical studies and correlate sets of genes to a new treatment s effectiveness. If we are unable to demonstrate the applicability of our test to new treatments, then sales of our test could decline, which would harm our revenues.

Our rights to use technologies licensed from third parties are not within our control, and we may not be able to sell our products if we lose our existing rights or cannot obtain new rights on reasonable terms.

We license from third parties technology necessary to develop our products. For example, we license technology from Roche that we use to analyze genes for possible inclusion in our tests and that we use in our clinical reference laboratory to conduct our test. In return for the use of a third party s technology, we may agree to pay the licensor royalties based on sales of our products. Royalties are a component of cost of product revenues and impact the margin on our test. We may need to license other technology to commercialize future products. Our business may suffer if these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary licenses on acceptable terms. Companies that attempt to replicate our tests could be set up in countries that do not recognize our intellectual property. Such companies could send test results into the United States and therefore reduce sales of our tests.

Our competitive position depends on maintaining intellectual property protection.

Our ability to compete and to achieve and maintain profitability depends on our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of patents, patent applications, copyrights, trademarks, and confidentiality, material data transfer, license and invention assignment agreements to protect our intellectual property rights. We also rely upon trade secret laws to protect unpatented know-how and continuing

technological innovation. Our intellectual property strategy is intended to develop and maintain our competitive position. Patents may be granted to us jointly with other organizations, and while we may have a right of first refusal, we cannot guarantee that a joint owner will not license rights to another party, and cannot guarantee that a joint owner will cooperate with us in the enforcement of patent rights.

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As of December 31, 2008, we had two issued patents in the U.S. covering genes and methods that are components of the Onco*type* DX assay, one of which was issued jointly to us and to the National Surgical Adjuvant Breast and Bowel Project, or NSABP. Our pending patent applications may not result in issued patents, and we cannot assure you that our issued patent or any patents that might ultimately be issued by the U.S. Patent and Trademark Office will protect our technology. Any patents that may be issued to us might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

From time to time, the United States Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office may change the standards of patentability and any such changes could have a negative impact on our business. In addition, competitors may develop their own versions of our test in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages.

We have received notices of claims of infringement or misuse of other parties proprietary rights in the past and may from time to time receive additional notices. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or the validity of our patents, will not be asserted or prosecuted against us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management s attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party s patent) to the party claiming infringement, develop non-infringing technology, stop selling our test or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, revising our test to include the non-infringing technologies would require us to re-validate our test, which would be costly and time-consuming. Also, we may be unaware of pending patent applications that relate to our test. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our test or using technology that contains the allegedly infringing intellectual property, which could harm our business.

It is possible that a third party or patent office might take the position that one or more patents or patent applications constitute prior art in the field of genomic-based diagnostics. In such a case, we might be required to pay royalties, damages and costs to firms who own the rights to these patents, or we might be restricted from using any of the inventions claimed in those patents.

If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve profitability.

Our principal competition comes from existing diagnostic methods used by pathologists and oncologists. These methods have been used for many years and are therefore difficult to change or supplement. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which facilitates adoption more readily than tests like

Onco*type* DX that are performed outside the pathology laboratory. In addition, few diagnostic methods are as expensive as Onco*type* DX.

We also face competition from many public and private companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast cancer, such as Celera Corporation, Clarient Diagnostic Services, Agendia B.V., Applied Genomics, bioTheranostics Incorporated, Exagen and

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University Genomics. Commercial laboratories with strong distribution networks for diagnostic tests, such as Genzyme Corporation, Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, may become competitors. Other potential competitors include companies that develop diagnostic tests such as Bayer Diagnostics, a division of Siemens AG, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd, and Veridex LLC, a Johnson & Johnson company, as well as other companies and academic and research institutions. Our competitors may invent and commercialize technology platforms that compete with ours. In addition, in December 2005, the federal government allocated a significant amount of funding to The Cancer Genome Atlas, a project aimed at developing a comprehensive catalog of the genetic mutations and other genomic changes that occur in cancers and maintaining the information in a free public database. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and these products may compete with ours. In addition, competitors may develop their own versions of our test in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

Our test is considered relatively expensive for a diagnostic test. We increased the list price of our test from $3,650 to $3,820 effective July 1, 2008, and we may raise prices in the future. This could impact reimbursement of and demand for Onco*type* DX. Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that could be viewed by physicians and payors as functionally equivalent to our test, which could force us to lower the list price of our test and impact our operating margins and our ability to achieve profitability. Some competitors have developed tests cleared for marketing by FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than Onco*type* DX, and that may discourage adoption and reimbursement of our test. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our test, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability and could cause the market price of our common stock to decline.

Our research and development efforts will be hindered if we are not able to contract with third parties for access to archival tissue samples.

Under standard clinical practice in the United States, tumor biopsies removed from patients are chemically preserved and embedded in paraffin wax and stored. Our clinical development relies on our ability to secure access to these archived tumor biopsy samples, as well as information pertaining to their associated clinical outcomes. Others have demonstrated their ability to study archival samples and often compete with us for access. Additionally, the process of negotiating access to archived samples is lengthy since it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to archival tumor tissue samples with hospitals and collaborators, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

If we cannot maintain our current clinical collaborations and enter into new collaborations, our product development could be delayed.

We rely on and expect to continue to rely on clinical collaborators to perform a substantial portion of our clinical trial functions. If any of our collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the research, development or commercialization of the products contemplated by the collaboration could be delayed or terminated. If any of our collaboration agreements are terminated, or if we are unable to renew those collaborations on acceptable terms, we would be required to seek alternative collaborations. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and

these collaborations may not be successful.

In the past, we have entered into clinical trial collaborations with highly regarded organizations in the cancer field including, for example, NSABP. Our success in the future depends in part on our ability to enter into agreements with other leading cancer organizations. This can be difficult due to internal and external constraints

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placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for a test such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any product that may result from a collaboration.

From time to time we expect to engage in discussions with potential clinical collaborators which may or may not lead to collaborations. However, we cannot guarantee that any discussions will result in clinical collaborations or that any clinical studies which may result will be enrolled or completed in a reasonable time frame or with successful outcomes. Once news of discussions regarding possible collaborations are known in the medical community, regardless of whether the news is accurate, failure to announce a collaborative agreement or the entity s announcement of a collaboration with an entity other than us may result in adverse speculation about us, our product or our technology, resulting in harm to our reputation and our business.

The loss of key members of our senior management team or our inability to retain highly skilled scientists, clinicians and salespeople could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical to us as we continue to develop our technologies and testing processes and as we attempt to transition to a company with more than one commercialized product. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including geneticists, licensed laboratory technicians, chemists, biostatisticians and engineers. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in oncology and close relationships with medical oncologists, surgeons, pathologists and other hospital personnel. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our products. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our discovery, development and sales programs. All of our employees are at-will employees, which means that either we or the employee may terminate their employment at any time.

If our sole laboratory facility becomes inoperable, we will be unable to perform our test and our business will be harmed.

We do not have redundant clinical reference laboratory facilities outside of Redwood City, California. Redwood City is situated near earthquake fault lines. Our facility and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for

damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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In order to rely on a third party to perform our tests, we could only use another facility with established state licensure and CLIA accreditation under the scope of which Onco*type* DX could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing to adopt Onco*type* DX and comply with the required procedures, that this laboratory would be willing to perform the tests for us on commercially reasonable terms, or that it would be able to meet our quality standards. In order to establish a redundant clinical reference laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility opened by us would be subject to certification under CLIA and licensed by several states, including California and New York, which can take a significant amount of time and result in delays in our ability to begin operations.

We are dependent on our information technology and telecommunications systems, and any failure of these systems could harm our business.

We depend on information technology, or IT, and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider is dependent upon telecommunications and data systems provided by outside vendors and information it receives from us on a regular basis. These IT and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities, and our general and administrative activities. Failures or significant downtime of our IT or telecommunications systems or those used by our third-party service providers could prevent us from processing tests, providing test results to physicians, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of IT or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our product revenues.

Changes in healthcare policy could subject us to additional regulatory requirements that may interrupt sales of Oncotype DX and increase our costs.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments. We developed our commercialization strategy for Onco*type* DX based on existing healthcare policies. Changes in healthcare policy, such as changes in the FDA regulatory policy for LDTs, the creation of broad limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially interrupt the sales of Onco*type* DX, increase costs and divert management s attention. For example, in 1989, the U.S. Congress passed federal self-referral prohibitions commonly known as the Stark Law, significantly restricting, regulating and changing laboratories relationships with physicians. In addition, selling our tests outside of the United States makes us subject to applicable foreign regulatory requirements, which may also change over time. We cannot predict what changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

We rely on a limited number of suppliers or, in some cases, a sole supplier, for some of our laboratory instruments and materials and may not be able to find replacements in the event our suppliers no longer supply that equipment or those materials.

We rely solely on Applied Biosystems, a division of Life Technologies Corporation, to supply some of the laboratory equipment on which we perform our tests. We periodically forecast our needs for laboratory equipment and enter into standard purchase orders with Applied Biosystems based on these forecasts. We believe that there are relatively few

equipment manufacturers other than Applied Biosystems that are currently capable of supplying the equipment necessary for Onco*type* DX. Even if we were to identify other suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from Applied Biosystems the quality and quantity of equipment

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we require for Onco*type* DX, we may need to reconfigure our test process, which would result in delays in commercialization or an interruption in sales. If any of these events occur, our business and operating results could be harmed. Additionally, if Applied Biosystems deems us to have become uncreditworthy, it has the right to require alternative payment terms from us, including payment in advance. We are also required to indemnify Applied Biosystems against any damages caused by any legal action or proceeding brought by a third party against Applied Biosystems for damages caused by our failure to obtain required approval with any regulatory agency.

We also rely on several sole suppliers for certain laboratory materials which we use to perform our tests. While we have developed alternate sourcing strategies for these materials, we cannot be certain that these strategies will be effective. If we should encounter delays or difficulties in securing these laboratory materials, delays in commercialization or an interruption in sales could occur.

We may be unable to manage our future growth effectively, which would make it difficult to execute our business strategy.

Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place strain on our administrative and operational infrastructure, including customer service and our clinical reference laboratory. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our test could lead to the filing of product liability claims if someone were to allege that our test failed to perform as it was designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, physicians sometimes order Onco*type* DX for patients who do not have the same specific clinical attributes indicated on the Onco*type* DX report form as those for which the test provides clinical experience information from validation studies. It is our practice to offer medical consultation to physicians ordering Onco*type* DX for such patients, including ER- patients and male breast cancer patients. A product liability or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we believe that our existing product and professional liability insurance is adequate, we cannot assure you that our insurance would fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation, result in the recall of our products, or cause current collaborators to terminate existing agreements and potential collaborators to seek other partners, any of which could impact our results of operations.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials, hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may be significant and could

negatively affect our operating results.

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International expansion of our business may expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy contemplates international expansion, including establishing direct sales and physician outreach and education capabilities outside of the United States and expanding our relationship with distributors. In February 2009, we established a subsidiary in Geneva, Switzerland and we may establish operations in other countries in the future. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our test in various countries;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors activities that may fall within the purview of the Foreign Corrupt Practice Act, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenues and results of operations.

Our dependence on distributors for sales of Oncotype DX outside of the U.S. could limit or prevent us from selling our test in other markets and from realizing long-term international revenue growth.

We do not have sales personnel outside of the U.S. but instead rely on distributors. As of February 2009, we had exclusive distribution agreements for Onco*type* DX in several countries outside of the U.S., and we may enter into other similar arrangements in other countries in the future. We intend to grow our business internationally, and to do so we may need to attract additional distributors to expand the territories in which we sell Onco*type* DX. Distributors may not commit the necessary resources to market and sell Onco*type* DX to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize long-term international revenue growth. Regulatory requirements, costs of doing business outside of the United States and the reimbursement process in foreign markets may also impact our revenues from international sales or impact our ability to increase international sales in the future.

We may acquire other businesses or form joint ventures that could harm our operating results, dilute our stockholders ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings or distribution. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of collaborations, strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions

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in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. The market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy, and this excessive volatility may continue for an extended period of time. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our marketable securities are subject to risks that could adversely affect our overall financial position.

We invest our cash in accordance with an established internal policy in instruments which historically have been highly liquid and carried relatively low risk. However, with recent credit market conditions, similar types of investments have experienced losses in value or liquidity issues which differ from their historical pattern. Should a portion of our marketable securities lose value or have their liquidity impaired, it could adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing, if available, may not be available on commercially attractive terms.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and technologies.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise capital to, among other things:

sustain commercialization of our initial test, enhancements to that test or any future tests we may develop;

increase our selling and marketing efforts to drive market adoption and address competitive developments;

further expand our clinical reference laboratory operations;

expand our technologies into other areas of cancer;

fund our clinical validation study activities;

expand our research and development activities;

acquire or license technologies; and

finance capital expenditures and our general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

the level of research and development investment required to maintain and improve our technology position;

costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

our need or decision to acquire or license complementary technologies or acquire complementary businesses;

changes in product development plans needed to address any difficulties in commercialization;

changes in the regulatory environment, including any decision by FDA to regulate our activities;

competing technological and market developments;

the rate of progress in establishing reimbursement arrangements with third-party payors; and

changes in regulatory policies or laws that affect our operations.

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If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. The credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities.

We must implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy public company reporting requirements, which will increase our costs and require additional management resources.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission. Compliance with Section 404 of the Sarbanes-Oxley Act and other requirements has increased our costs and required additional management resources. We will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy existing reporting requirements. If we fail to maintain or implement adequate controls, if we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting in future Form 10-K filings, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting in future Form 10-K filings, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

ITEM 1B. ***Unresolved Staff Comments***.

None.

ITEM 2. ***Properties***.

At December 31, 2008, we occupied approximately 96,000 square feet of laboratory and office space in Redwood City, California under operating leases that expire in February 2012. We believe that these facilities are adequate to meet our business requirements for the near-term and that additional space, when needed, will be available on commercially reasonable terms.

ITEM 3. ***Legal Proceedings***.

We were not a party to any legal proceedings, other than immaterial proceedings in the ordinary course of our business, at December 31, 2008, or at the date of this report.

ITEM 4. ***Submission of Matters to a Vote of Security Holders***.

No matters were submitted to a vote of security holders during the fourth quarter of 2008.

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Executive Officers of the Registrant

The names of our executive officers and their ages as of March 1, 2009, are as follows:

Name	Age	Position
Randal W. Scott, Ph.D.	51	Executive Chairman of the Board
Kimberly J. Popovits	50	President and Chief Executive Officer and Director
G. Bradley Cole	53	Chief Operating Officer and Chief Financial Officer; Secretary
Steven Shak, M.D.	58	Chief Medical Officer
Joffre B. Baker, Ph.D.	61	Chief Scientific Officer

Randal W. Scott, Ph.D., has served as our Executive Chairman of the Board since January 2009, Chairman of the Board and Chief Executive Officer since our inception in August 2000 until December 2008, President from August 2000 until February 2002, Chief Financial Officer from December 2000 until April 2004, and Secretary from August 2000 until December 2000 and from May 2003 until February 2005. Dr. Scott was a founder of Incyte Corporation, a genomic information company, and served Incyte in various roles, including Chairman of the Board from August 2000 to December 2001, President from January 1997 to August 2000, and Chief Scientific Officer from March 1995 to August 2000. Dr. Scott holds a B.S. in Chemistry from Emporia State University and a Ph.D. in Biochemistry from the University of Kansas.

Kimberly J. Popovits has served as our President and Chief Executive Officer since January 2009, President and Chief Operating Officer since February 2002 and as a director since March 2002. From November 1987 to February 2002, Ms. Popovits served in various roles at Genentech, Inc., a biotechnology company, most recently serving as Senior Vice President, Marketing and Sales from February 2001 to February 2002, and as Vice President, Sales from October 1994 to February 2001. Prior to joining Genentech, she served as Division Manager, Southeast Region, for American Critical Care, a division of American Hospital Supply, a supplier of health care products to hospitals. Ms. Popovits holds a B.A. in Business from Michigan State University.

G. Bradley Cole has served as our Chief Operating Officer and Chief Financial Officer since January 2009, Executive Vice President, Operations from January 2008 until December 2008, Executive Vice President and Chief Financial Officer from July 2004 until December 2008 and Secretary since February 2005. From December 1997 to May 2004, he served in various positions at Guidant Corporation, a medical device company, most recently serving as Vice President, Finance and Business Development for the Endovascular Solutions Group from January 2001 until May 2004. From July 1994 to December 1997, Mr. Cole was Vice President, Finance and Chief Financial Officer of Endovascular Technologies, Inc., a medical device company that was acquired by Guidant Corporation. From December 1988 to February 1994, he served as Vice President, Finance and Chief Financial Officer of Applied Biosystems Incorporated, a life sciences systems company. Mr. Cole holds a B.S. in Business from Biola University and an M.B.A. from San Jose State University.

Steven Shak, M.D., has served as our Chief Medical Officer since December 2000. From July 1996 to October 2000, Dr. Shak served in various roles in Medical Affairs at Genentech, most recently as Senior Director and Staff Clinical Scientist. From November 1989 to July 1996, Dr. Shak served as a Director of Discovery Research at Genentech, where he was responsible for Pulmonary Research, Immunology, and Pathology. Prior to joining Genentech, Dr. Shak was an Assistant Professor of Medicine and Pharmacology at the New York University School of Medicine. Dr. Shak holds a B.A. in Chemistry from Amherst College and an M.D. from the New York University School of Medicine, and completed his post-doctoral training at the University of California, San Francisco.

Joffre B. Baker, Ph.D., has served as our Chief Scientific Officer since December 2000. From March 1997 to October 2000, Dr. Baker served as the Vice President for Research Discovery at Genentech. From March 1993 to October 2000, Dr. Baker oversaw Research Discovery at Genentech, which included the departments of Cardiovascular Research, Oncology, Immunology, Endocrinology, and Pathology. From July 1991 to October 1993, he served as Genentech s Director of Cardiovascular Research. Prior to joining Genentech, Dr. Baker was a member of the faculty of the Department of Biochemistry at the University of Kansas. He holds a B.S. in Biology and Chemistry from the University of California, San Diego and a Ph.D. in Biochemistry from the University of Hawaii.

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PART II

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

Our common stock, par value $0.0001, is traded on the NASDAQ Global Market under the symbol GHDX. The following table sets forth the range of high and low sales prices for our common stock for the periods indicated:

	2008			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Stock price high	$ 27.02	$ 22.42	$ 25.50	$ 22.91
Stock price low	$ 16.45	$ 16.58	$ 18.86	$ 16.00

	2007			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Stock price high	$ 24.68	$ 19.70	$ 22.25	$ 26.17
Stock price low	$ 16.47	$ 14.80	$ 18.25	$ 19.12

According to the records of our transfer agent, we had 115 stockholders of record as of February 28, 2009.

Dividends

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Our board of directors will determine future cash dividends, if any. There are currently no contractual restrictions on our ability to pay dividends.

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Stock Performance Graph

The following information is not deemed to be soliciting material or to be filed with the Securities and Exchange Commission or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934 or to the liabilities of Section 18 of the Securities Exchange Act of 1934, and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent we specifically incorporate it by reference into such a filing.

Set forth below is a line graph showing the cumulative total stockholder return (change in stock price plus reinvested dividends) assuming the investment of $100 on September 29, 2005 (the day of our initial public offering) in each of our common stock, the NASDAQ Market Index and the NASDAQ Biotechnology Index for the period commencing on September 29, 2005 and ending on December 31, 2008. The comparisons in the table are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of future performance of our common stock.

COMPARISON OF CUMULATIVE TOTAL RETURN
AMONG GENOMIC HEALTH INC.,
NASDAQ MARKET INDEX AND PEER GROUP INDEX

	September 29, 2005	December 31, 2005	December 31, 2006	December 31, 2007	December 31, 2008
Genomic Health, Inc.	$ 100.00	$ 77.53	$ 158.30	$ 192.68	$ 165.79
NASDAQ Market Index	$ 100.00	$ 102.82	$ 113.47	$ 124.76	$ 74.00
NASDAQ Biotechnology Index	$ 100.00	$ 104.49	$ 104.49	$ 104.76	$ 98.42

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ITEM 6. ***Selected Financial Data***.

The following selected consolidated financial data should be read together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this report. The selected consolidated balance sheets data at December 31, 2008 and 2007 and the selected consolidated statements of operations data for each year ended December 31, 2008, 2007 and 2006 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The selected consolidated balance sheets data at December 31, 2006, 2005 and 2004 and the selected consolidated statements of operations data for each year ended December 31, 2005 and 2004 have been derived from our audited consolidated financial statements not included in this report. Historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product revenues	$ 108,658	$ 62,745	$ 27,006	$ 4,823	$ 227
Contract revenues	1,921	1,282	2,168	379	100
Total revenues	110,579	64,027	29,174	5,202	327
Operating expenses(1):					
Cost of product revenues	27,185	17,331	9,908	6,249	1,828
Research and development	28,624	22,053	12,841	9,465	10,040
Selling and marketing	46,668	36,456	24,625	15,348	9,856
General and administrative	25,617	17,849	12,765	6,485	3,869
Total operating expenses	128,094	93,689	60,139	37,547	25,593
Loss from operations	(17,515)	(29,662)	(30,965)	(32,345)	(25,266)
Interest and other income, net	1,365	2,370	2,045	984	271
Loss before income tax benefit	(16,150)	(27,292)	(28,920)	(31,361)	(24,995)
Income tax benefit	61				
Net loss	$ (16,089)	$ (27,292)	$ (28,920)	$ (31,361)	$ (24,995)
Basic and diluted net loss per share	$ (0.57)	$ (1.02)	$ (1.18)	$ (4.15)	$ (13.82)
Weighted-average shares used in computing basic and diluted net loss per share	28,297,705	26,759,798	24,508,845	7,557,106	1,808,022

(1) Includes non-cash charges for employee stock-based compensation expense as follows:

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Cost of product revenues	$ 491	$ 375	$ 167	$ 53	$ 5
Research and development	2,913	1,882	821	323	42
Selling and marketing	2,622	1,876	779	274	38
General and administrative	3,112	2,152	1,137	426	106
Total	$ 9,138	$ 6,285	$ 2,904	$ 1,076	$ 191

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On January 1, 2006, we adopted Statement of Financial Accounting Standard No. 123R, *Share-based Payment*, using the modified prospective method. Prior to 2006, stock-based compensation was recognized in accordance with Accounting Principles Board Opinion No. 25.

	At December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents and short-term investments	$ 56,669	$ 68,360	$ 44,215	$ 69,527	$ 38,275
Working capital	52,692	63,948	37,516	65,801	36,771
Total assets	86,689	87,929	58,024	75,799	41,538
Notes payable, current portion	1,814	2,687	2,547	1,052	
Notes payable, long-term portion	225	2,039	4,726	2,621	
Convertible preferred stock					103,212
Accumulated deficit	(168,484)	(152,395)	(125,103)	(96,183)	(64,822)
Total stockholders equity (deficit)	66,175	71,166	41,829	67,517	(64,154)

ITEM 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes included in Item 8 of this report. Historical results are not necessarily indicative of future results.

Business Overview

We are a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. Our diagnostic test, Onco*type* DX, is used for breast cancer patients to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit and is conducted at our clinical reference laboratory in Redwood City, California. Effective July 1, 2008, we increased the list price of our test from $3,650 to $3,820. Substantially all of our historical revenues have been derived from the sale of Onco*type* DX ordered by physicians in the United States.

Adoption and Reimbursement

For the year ended December 31, 2008, more than 39,600 test reports were delivered for use in treatment planning, compared to more than 24,450 and more than 14,500 test reports delivered for the years ended December 31, 2007 and 2006, respectively. As of December 31, 2008, more than 85,000 tests had been delivered for use in treatment planning by more than 7,500 physicians. We believe increased demand resulted from the inclusion of Onco*type* DX in the clinical practice guidelines of the American Society of Clinical Oncologists, or ASCO, and the National Comprehensive Cancer Network, or NCCN, publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use and reimbursement of Onco*type* DX, clinical presentations at major symposia, and our ongoing commercial efforts. However, this increased demand is not necessarily indicative of future demand, and we cannot assure you that this level of increased demand can be sustained or that publication of articles, future appearances or presentations at medical conferences or increased commercial efforts will have a similar impact on demand for Onco*type* DX. We believe that each year we may experience slower demand for our test in the second and third calendar quarters, which may be attributed to physicians, surgeons and patients scheduling vacations during this

time.

We depend upon third-party payors to provide reimbursement for our test. Accordingly, we have focused substantial resources on obtaining reimbursement coverage from third-party payors. As of February 2009, more than 90% of all U.S. insured lives were covered by health plans that provide reimbursement for Onco*type* DX for patients with N-, ER+ disease through contracts, agreements or policy decisions.

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In order to enhance the clinical utility of Onco*type* DX, we introduced quantitative gene expression reporting for estrogen receptor, or ER, and progesterone receptor, or PR, genes with the Onco*type* DX report in February 2008 and for the human epidermal growth factor receptor 2, or HER2, gene in September 2008. In the second half of 2008, we experienced an increase in usage of Onco*type* DX for N+ patients. While some payors provide coverage for the use of Onco*type* DX in patients with lymph node micrometastasis (greater than 0.2mm, but not greater than 2.0 mm in size), substantially all of our existing reimbursement coverage is limited to women with early-stage N-, ER+ breast cancer. We may not be able to obtain reimbursement coverage for Onco*type* DX for breast cancer patients with N+, ER+ disease.

Our domestic sales, marketing and reimbursement efforts are focused on direct interaction with medical and surgical oncologists, pathologists and payors. In January 2009, we hired an additional 20 U.S. sales representatives, increasing our domestic sales force to a total of 80 sales representatives. We have also continued to expand internationally. As of February 2009, we had received test samples from 40 countries, completed or initiated multiple international studies and established exclusive distribution agreements for Onco*type* DX with partners in eight countries outside of the U.S. We established a subsidiary in Geneva, Switzerland in February 2009 and have appointed lead executives in Europe and in Asia to support our international efforts. We do not expect international product revenues to comprise a significant portion of our total revenues for at least the next three years.

Product Pipeline

We are investigating the utility of Onco*type* DX in patients with ductal carcinoma in situ, or DCIS, which generally refers to a pre-invasive tumor with reduced risk of recurrence. We plan to evaluate the use of the Onco*type* DX gene panel and also seek to identify other genes that may be used for treatment planning in DCIS. We are also conducting studies of Onco*type* DX with clinical samples from breast cancer patients who were treated with aromatase inhibitors.

Outside of breast cancer, we are conducting an independent clinical validation study in stage II colon cancer for our 18-gene colon cancer assay, utilizing more than 1,200 patient samples from an international trial which examined the benefit associated with 5-fluorouracil/leucovorin chemotherapy. We anticipate reporting results of this validation study in the second half of 2009. We do not currently expect to commercialize a test for colon cancer until 2010.

Economic Environment

Continuing concerns over inflation, deflation, energy costs, geopolitical issues, the availability and cost of credit, the Federal stimulus plan, Federal budget proposals, the U.S. mortgage market and a declining real estate market in the U.S. have contributed to increased volatility and diminished expectations for the global economy and expectations of slower global economic growth going forward. These factors, combined with volatile oil prices, declining business and consumer confidence, a declining stock market and increased unemployment, have precipitated an economic slowdown and recession. We evaluated the impact of this environment on our cash management, cash collection activities and volume of tests delivered.

As of the date of this report, we have not experienced a loss of principal on any of our investments, and we expect that we will continue to be able to access or liquidate these investments as needed to support our business activities. From time to time, we monitor the financial position of our significant third-party payors, which include Medicare and managed care companies. As of the date of this report, we do not expect the current economic environment to have a material negative impact on our ability to collect payments from our third-party payors in the foreseeable future. The economic slowdown could negatively impact the volume of tests we deliver if patients lose healthcare coverage, delay medical checkups or are unable to pay for our test.

We intend to continue to assess the impact of the economic environment on our business activities. If the economic climate in the U.S. does not improve or continues to deteriorate, our cash position, cash collection activities and volume of tests delivered could be negatively impacted and we could experience lower revenues.

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Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our financial statements.

Revenue Recognition

We exercise judgment in determining whether revenue is recognized on an accrual basis when test results are delivered or on a cash basis when cash is received from the payor. Our revenues for tests performed are recognized when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. We assess whether the fee is fixed or determinable based on the nature of the fee charged for the products or services delivered and existing contractual agreements. When evaluating collectibility, we consider whether we have sufficient history to reliably estimate a payor s individual payment patterns. Based upon at least several months of payment history, we review the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the contracted payment amount. To the extent all criteria set forth above are not met, including where there is no evidence of payment history at the time test results are delivered, product revenues are recognized on a cash basis when cash is received from the payor.

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recognized on a contract-specific basis. Under certain contracts, revenues are recognized as costs are incurred or assays are processed. We may exercise judgment when estimating full-time equivalent level of effort, costs incurred and time to project completion. For certain contracts, we utilize the performance-based method of revenue recognition, which requires that we estimate the total amount of costs to be expended for a project then recognize revenue equal to the portion of costs expended to date. The estimated total costs to be expended are necessarily subject to revision from time-to-time as the underlying facts and circumstances change.

Allowance for Doubtful Accounts

We accrue an allowance for doubtful accounts against our accounts receivable based on estimates consistent with historical payment experience. Our allowance for doubtful accounts is evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. As of December 31, 2008 and 2007, our allowance for doubtful accounts was $881,000 and $133,000, respectively. The year over year increase in our allowance for doubtful accounts reflected the impact of moving several third-party payors from a cash basis to an accrual basis.

Research and Development Expenses

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: salaries and benefits, allocated overhead and facility occupancy costs, contract services and other outside costs, and costs to acquire in-process research and development projects and technologies that have no alternative future use. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies. Research and development costs are expensed as incurred.

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Prior to January 1, 2008, we recognized non-refundable advance payments for goods and services to be used for future research and development activities as an expense when payments were made. Beginning January 1, 2008, these payments are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed in accordance with Emerging Issues Task Force Issue No. 07-3, *Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities*, or EITF 07-3. As a result of our adoption of EITF 07-3, our research and development collaboration expenses and net loss decreased by $258,000 for the year ended December 31, 2008. Our net loss per share decreased by $0.01 for the year ended December 31, 2008. We expect to recognize these deferred and capitalized amounts as expense in future periods as the related services are delivered.

We enter into collaboration and clinical trial agreements with clinical collaborators and record these costs as research and development expenses. We record accruals for estimated study costs comprised of work performed by our collaborators under contract terms.

All potential future product programs outside of breast and colon cancer are in the research or early development phase. The expected time frame in which a test for one of these other cancers can be brought to market is uncertain given the technical challenges and clinical variables that exist between different types of cancers. In 2008, we began maintaining information regarding costs incurred for activities performed under certain contracts with biopharmaceutical and pharmaceutical companies. However, we do not generally record or maintain information regarding costs incurred in research and development on a program-specific basis. Our research and development staff and associated infrastructure resources are deployed across several programs. Many of our costs are thus not attributable to individual programs. As a result, we are unable to determine the duration and completion costs of our research and development programs or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product.

Stock-based Compensation Expense

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R, which addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. Under the provisions of SFAS 123R, our employee stock-based compensation is estimated at the date of grant based on the fair value of the award using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period. The application of SFAS 123R requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Black-Scholes valuation method requires the use of estimates such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value stock-based compensation. As of January 2008, our assumptions regarding expected volatility are based on the historical volatility of our common stock. Prior to January 2008, our assumptions regarding expected volatility were based primarily on comparable peer data because our common stock had been publicly traded for less than two years. The expected life of options is estimated based on historical option exercise data and assumptions related to unsettled options. Expected option forfeiture rates are based on historical data, and compensation expense is adjusted for actual results.

As required under SFAS 123R, we review our valuation assumptions on an ongoing basis, and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. See Note 10, Stock-Based Compensation, in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K for more information.

Results of Operations

Comparison of Years Ended December 31, 2008, 2007 and 2006

We recorded net loss for the years ended December 31, 2008, 2007 and 2006 of $16.1 million, $27.3 million and $28.9 million, respectively. On a basic and diluted per share basis, net loss was $0.57, $1.02 and $1.18 for the years ended December 31, 2008, 2007 and 2006, respectively.

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Revenues

We derive our revenues primarily from product sales and, to a lesser extent, from contract research arrangements. We operate in one industry segment. Our product revenues are derived solely from the sale of our Onco*type* DX test. Payors are billed upon generation and delivery of a Recurrence Score report to the physician. Product revenues are recorded on a cash basis unless a contract or policy is in place with the payor at the time of billing and collectibility is reasonably assured. Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recorded as contractual obligations are completed.

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Product revenues	$ 108,658	$ 62,745	$ 27,006
Contract revenues	1,921	1,282	2,168
Total revenues	$ 110,579	$ 64,027	$ 29,174
Year over year dollar increase in product revenues	$ 45,913	$ 35,739	
Year over year percentage increase in product revenues	73%	132%	

The year over year increases in product revenues resulted from increased adoption, as evidenced by a 62% increase in test volume for 2008 compared to 2007 and a 61% increase in test volume for 2007 compared to 2006, expanded reimbursement coverage, resulting in increases in the amount paid per test, and increases in revenues recorded on an accrual basis. Approximately $55.1 million, or 51%, of product revenues for the year ended December 31, 2008 were recorded on an accrual basis and recognized at the time the test results were delivered, compared to $23.0 million, or 37%, and $10.8 million, or 40%, of product revenues for the years ended December 31, 2007 and 2006, respectively. Of the tests delivered, 42% were on an accrual basis for the year ended December 31, 2008, compared to 26% and 21% of tests delivered for the years ended December 31, 2007 and 2006, respectively. For all periods, the balance of product revenues was recognized upon cash collection as payments were received.

Product revenues from Medicare payments for the year ended December 31, 2008 were $23.7 million, or 22% of product revenues, compared to $14.3 million, or 23%, and $12.7 million, or 47%, for the years ended December 31, 2007 and 2006, respectively. Medicare revenue for the year ended December 31, 2006 included $4.7 million of payments for services provided to Medicare patients prior to Medicare s February 27, 2006 effective coverage date for Onco*type* DX. Product revenues from United HealthCare Insurance Company payments were $9.8 million, or 9% of product revenues, for the year ended December 31, 2008 compared to $8.2 million, or 13% of product revenues, for the year ended December 31, 2007. There were no product revenues from United HealthCare Insurance Company payments for the year ended December 31, 2006.

Contract revenues were $1.9 million, $1.3 million and $2.2 million for the years ended December 31, 2008, 2007 and 2006, respectively. Contract revenues represented studies assessing our gene expression technology or collaborative work in gene selection and protocol design with our pharmaceutical partners. The increase in contract revenues for 2008 compared to 2007 included the recognition of $1.4 million in 2008 related to the completion of a contract. The decrease in contract revenues for 2007 compared to 2006 was due to project timing for ongoing research and development collaboration activities. We expect that our contract revenues will continue to fluctuate based on the number and timing of studies being conducted.

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Cost of Product Revenues

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Tissue sample processing costs	$ 18,998	$ 12,071	$ 7,568
Employee stock-based compensation	491	375	167
Total tissue sample processing costs	19,489	12,446	7,735
License fees	7,696	4,885	2,173
Total cost of product revenues	$ 27,185	$ 17,331	$ 9,908
Year over year dollar increase	$ 9,854	$ 7,423	
Year over year percentage increase	57%	75%	

Cost of product revenues represents the cost of materials, direct labor, equipment and infrastructure expenses associated with processing tissue samples (including histopathology, anatomical pathology, paraffin extraction, reverse transcription polymerase chain reaction, or RT-PCR, quality control analyses and shipping charges to transport tissue samples) and license fees. Infrastructure expenses include allocated facility occupancy and information technology costs. Costs associated with performing our test are recorded as tests are processed. Costs recorded for tissue sample processing represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. Royalties for licensed technology calculated as a percentage of product revenues and fixed annual payments relating to the launch and commercialization of Onco*type* DX are recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

Test volume increased 62% from 2007 to 2008 and 61% from 2006 to 2007, driving the $6.9 million, or 57%, and $4.5 million, or 60%, year over year increases in tissue sample processing costs. The $2.8 million, or 57%, and $2.7 million, or 125%, year over year increases in license fees included higher royalties primarily driven by year over year increases in product revenues of 73% and 132%, respectively. We expect the cost of product revenues to increase to the extent we process more tests.

Research and Development Expenses

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Personnel-related expenses	$ 16,534	$ 11,487	$ 6,211
Employee stock-based compensation	2,913	1,882	821
Collaboration expenses	1,433	1,320	1,486
Reagents and laboratory supplies	1,972	1,709	773
Infrastructure and all other costs	5,772	5,655	3,550

Total research and development expenses	$ 28,624	$ 22,053	$ 12,841
Year over year dollar increase	$ 6,571	$ 9,212	
Year over year percentage increase	30%	72%	

Research and development expenses represent costs incurred to develop our technology and carry out clinical studies and include personnel-related expenses, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated overhead and facility occupancy costs, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies.

The $6.6 million increase in research and development expenses for 2008 compared to 2007 included a $5.0 million increase in personnel-related expenses due primarily to an increase in headcount year over year, a

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$1.0 million increase in stock-based compensation and a $263,000 increase in costs incurred for reagents and laboratory supplies. The $9.2 million increase in research and development expenses for 2007 compared to 2006 included a $5.3 million increase in personnel-related expenses due primarily to an increase in headcount year over year, a $2.1 million increase in infrastructure expenses, including allocations for laboratory facilities expansion and improvements, a $1.1 million increase in employee stock-based compensation and a $936,000 increase in costs incurred for reagents and lab supplies. We expect that our research and development expenses will continue to increase as we increase investment in our product pipeline for a variety of cancers, including cancers other than breast and colon.

Selling and Marketing Expenses

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Personnel-related expenses	$ 21,208	$ 17,225	$ 11,371
Employee stock-based compensation	2,622	1,876	779
Promotional and marketing materials	10,961	8,972	7,437
Travel, meetings and seminars	6,086	5,294	2,910
Infrastructure and all other costs	5,791	3,089	2,128
Total selling and marketing expenses	$ 46,668	$ 36,456	$ 24,625
Year over year dollar increase	$ 10,212	$ 11,831	
Year over year percentage increase	28%	48%	

Our selling and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses associated with Onco*type* DX and infrastructure expenses, including allocated facility occupancy and information technology costs. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding our genomic technologies, how our Onco*type* DX test was developed and validated and the value of the quantitative information that Onco*type* DX provides. Selling and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of our scientific and economic publications related to Onco*type* DX.

The $10.2 million increase in selling and marketing expenses for 2008 compared to 2007 was primarily due to a $4.0 million increase in personnel-related expenses, reflecting our investment in our field sales and support organization, a $2.7 million increase in infrastructure and other expenses, including allocations for facilities expansion and improvements and medical affairs support for breast cancer product enhancements, a $2.0 million increase in promotional field and marketing expense, a $792,000 increase in travel-related expenses, primarily associated with field sales personnel, and a $746,000 increase in stock-based compensation. Of the $4.0 million increase in personnel-related expenses, $3.5 million was attributable to increases in salaries and related expenses and $528,000 was attributable to higher commissions and bonus payments related to increased product revenues.

The $11.8 million increase in selling and marketing expenses in 2007 compared to 2006 was due to a $5.9 million increase in personnel-related expenses, largely due to the expansion of our domestic field sales and support organization in the second half of 2006, $2.4 million in higher travel-related expenses primarily associated with field sales personnel, a $1.5 million increase in promotional field and marketing expense, a $1.1 million increase in stock-based compensation expense, and a $1.0 million increase in infrastructure expenses, including facilities

expansion and improvements. Of the $5.9 million increase in personnel-related expenses, $4.7 million was attributable to increases in salaries and related expenses, including the expansion of our domestic field sales force in July 2006, and, $1.2 million was attributable to higher commissions and bonus payments related to increased product revenues.

We expect that selling and marketing expenses will continue to increase in future periods as we continue to invest in our domestic field sales force and support organization and expand our commercial efforts in international

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markets. In January 2009, we hired an additional 20 U.S. sales representatives, increasing our domestic sales force by 33% to a total of 80 sales representatives.

General and Administrative Expenses

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Personnel-related expenses	$ 9,184	$ 6,053	$ 4,530
Employee stock-based compensation	3,112	2,152	1,137
Professional fees and all other costs	13,321	9,644	7,098
Total general and administrative expenses	$ 25,617	$ 17,849	$ 12,765
Year over year dollar increase	$ 7,768	$ 5,084	
Year over year percentage increase	44%	40%	

Our general and administrative expenses consist primarily of personnel-related expenses and professional fees and other costs, including legal fees, advisory and auditing expenses, billing and collection costs, bad debt expense and other professional and administrative costs and related infrastructure expenses, including allocated facility occupancy and information technology costs.

The $7.8 million increase in general and administrative expenses for 2008 compared to 2007 included a $3.1 million increase in personnel-related expenses due primarily to an increase in headcount year over year, a $1.4 million increase in bad debt expense related to growth in our aged accounts receivable balances, a $1.1 million increase in billing and collections expense related to an increase in the number of tests processed and cash collected, a $960,000 increase in stock-based compensation expense and a $768,000 increase in professional fees, due primarily to legal fees related to regulatory and other matters, and a $406,000 increase in infrastructure and related costs.

The $5.1 million increase in general and administrative expenses for 2007 compared to 2006 included a $1.5 million increase in personnel-related expense due primarily to an increase in headcount year over year, a $1.0 million increase in stock-based compensation and $966,000 in higher billing and collection fees paid to third-party billing and collection vendors. These increases were partially offset by a decrease in bad debt expense due to changes in our estimate of allowance for doubtful accounts, which resulted in a $115,000 credit to bad debt expense for the year ended December 31, 2007.

We expect general and administrative expenses to increase as we hire additional staff and incur other expenses to support the growth of our business and to the extent we spend more on fees for billing and collections as we process more tests.

Interest and Other Income

Interest and other income was $1.8 million for the year ended December 31, 2008 compared to $3.0 million and $2.5 million for the years ended December 31, 2007 and 2006, respectively. The decrease in interest and other income for 2008 compared to 2007 reflected decreased interest income due to lower average cash and short-term investment balances compared to the prior year, which reflected the investment of a portion of the proceeds from our May 2007 common stock offering, and lower market yields on our investments in 2008. The increase in interest and other

income for 2007 compared to 2006 was due to increased interest income from higher average short-term investment balances, resulting from our investment of a portion of the cash proceeds from our May 2007 public offering of common stock, and higher market yields on our investments in 2007.

We expect our interest and other income may continue to decrease if the overall decline in the interest rate environment related to the current economic crisis continues.

Interest Expense

Interest expense was $386,000 for the year ended December 31, 2008 compared to $678,000 and $446,000 for the years ended December 31, 2007 and 2006, respectively. We incur interest expense on our equipment financing established in March 2005. The $292,000 decrease in interest expense in 2008 compared to 2007 was due to lower

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average balances on these borrowings as we paid them down. The $232,000 increase in interest expense in 2007 compared to 2006 was due to higher average balances on these borrowings reflecting draws made on our equipment financing line in January 2007.

We expect our interest expense to decline as we continue to make payments on our equipment financing. We do not anticipate using additional equipment financing as a funding source in the next twelve months.

Liquidity and Capital Resources

As of December 31, 2008, we had an accumulated deficit of $168.5 million. We have not yet achieved profitability and anticipate that we will likely incur net losses for at least the next year. However, we cannot provide assurance as to when, if ever, we will achieve profitability. We expect that our research and development, selling and marketing and general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenues to achieve profitability.

	2008	2007	2006
		(In thousands)	
As of December 31:			
Cash, cash equivalents and short-term investments	$ 56,669	$ 68,360	$ 44,215
Working capital	52,692	63,948	37,516
For the year ended December 31:			
Cash provided by (used in):			
Operating activities	(818)	(18,706)	(20,733)
Investing activities	(26,167)	(4,744)	13,041
Financing activities	(1,008)	47,688	3,779
Capital expenditures (included in investing activities above)	(10,057)	(4,881)	(8,424)

Sources of Liquidity

At December 31, 2008, we had cash, cash equivalents and short-term investments of $56.7 million compared to $68.4 million at December 31, 2007. In accordance with our investment policy, available cash is invested in short-term, low-risk, investment-grade debt instruments. Our cash and short-term investments are held in a variety of interest-bearing instruments including money market accounts, obligations of U.S. government-sponsored entities, high-grade corporate bonds and commercial paper. At December 31, 2008, our holdings of obligations of U.S. government-sponsored entities consisted entirely of debt securities issued by the Federal Home Loan Bank, the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation.

Historically we have financed our operations primarily through sales of our equity securities and cash received in payment for our tests. In May 2007, we completed a public offering of our common stock, resulting in net proceeds of $49.7 million. At December 31, 2008, we had approximately $46.5 million of securities available for issuance under a shelf registration statement. Purchases of equipment and leasehold improvements have been partially financed through capital equipment financing arrangements. At December 31, 2008 and December 31, 2007, we had notes payable under these equipment financing arrangements of $2.0 million and $4.7 million, respectively. Our existing notes payable under these arrangements are scheduled to be fully paid by November 2010.

Cash Flows

Net cash used in operating activities was $818,000, $18.7 million and $20.7 million for the years ended December 31, 2008, 2007 and 2006, respectively. Net cash used in operating activities includes net loss adjusted for certain non-cash items and changes in assets and liabilities. The $17.9 million decrease in net cash used in operating activities from 2008 to 2007 was primarily due to a $15.1 million decrease in net loss excluding depreciation and stock-based compensation expense, a $2.6 million decrease in net cash used related to increases in deferred revenues, a $489,000 decrease in net cash used related to accounts payable and a $1.3 million increase in accrued expenses and other liabilities, partially offset by a $491,000 million increase in net cash used related to increases in accounts receivable and a $1.3 million increase in net cash used related to decreases in accrued compensation. The $2.0 million decrease in net cash used in operating activities from 2007 to 2006 was primarily due to a $6.4 million

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decrease in net loss excluding depreciation and stock-based compensation expense and a $489,000 decrease in net cash used related to increases in accrued expenses and other liabilities, partially offset by a $3.1 million increase in net cash used related to increases in accounts receivable, prepaid expenses and other assets and a $1.7 million increase in cash used due to a decrease in accounts payable.

Net cash used in investing activities was $26.2 million for the year ended December 31, 2008, compared to net cash used in investing activities of $4.7 million for the year ended December 31, 2007 and net cash provided by investing activities of $13.0 million for the year ended December 31, 2006. Our investing activities have consisted predominately of purchases and maturities of marketable securities and capital expenditures. The $21.5 million increase in net cash used in investing activities from 2007 to 2008 was due to a $16.3 million increase in net purchases of short-term investments as we invested a portion of the cash proceeds from our May 2007 public offering of common stock as well as a $5.2 million increase in capital expenditures for facility expansion and improvements. The $17.7 million increase in net cash used in investing activities from 2006 to 2007 was due to a $21.3 million increase in net purchases of short-term investments as we invested a portion of the cash proceeds from our May 2007 public offering of common stock, partially offset by a $3.5 million decrease in capital expenditures for facility expansion and improvements.

Net cash used in financing activities was $1.0 million for the year ended December 31, 2008, compared to net cash provided by financing activities of $47.7 million and $3.8 million for the years ended December 31, 2007 and 2006, respectively. Our financing activities include sales of our equity securities and capital equipment financing arrangements. The $48.7 million decrease in net cash provided by financing activities from 2007 to 2008 was primarily due to a decrease in proceeds from issuance of common stock. The $43.9 million increase in net cash provided by financing activities from 2006 to 2007 included net proceeds of $49.7 million from our May 2007 public offering of common stock, partially offset by a $6.1 million decrease in cash provided by capital equipment financing.

Contractual Obligations

The following table summarizes our significant contractual obligations as of December 31, 2008 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
	(In thousands)				
Notes payable obligations	$ 2,172	$ 1,934	$ 238	$	$
Non-cancelable operating lease obligations	5,167	1,520	3,357	290	
Total	$ 7,339	$ 3,454	$ 3,595	$ 290	$

Our notes payable obligations are for principal and interest payments on capital equipment financing. In March 2005, we entered into an arrangement to finance the acquisition of laboratory equipment, computer hardware and software, leasehold improvements and office equipment. In connection with this arrangement, we granted the lender a security interest in the assets purchased with these borrowings. Beginning in April 2006, we could prepay all, but not part, of any amounts owing under the arrangement so long as we also paid a 6% premium on the remaining outstanding principal balance. This premium was reduced to 5% in April 2007 and was further reduced to 4% in April 2008. As of

December 31, 2008, the outstanding principal balance under this arrangement was $2.2 million at annual interest rates ranging from 10.23% to 11.30%, depending upon the applicable note.

Our non-cancelable operating lease obligations are for laboratory and office space. In September 2005, we entered into a non-cancelable lease for 48,000 square feet of laboratory and office space in Redwood City, California. In January 2007, we entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space in a nearby location. Both leases expire in February 2012.

We are required to make a series of fixed annual payments under one of our collaboration agreements beginning on the date that we commercially launched Onco*type* DX. We made payments of $300,000, $300,000 and $475,000 in January 2006, 2007 and 2008, respectively. We are required to make additional payments of $475,000

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in each of 2009 through 2011. However, because either party may terminate the agreement upon 30 days prior written notice, these payments are not included in the table above.

We have also committed to make potential future payments to third parties as part of our collaboration agreements. Payments under these agreements generally become due and payable only upon achievement of specific project milestones. Because the achievement of these milestones is generally neither probable nor reasonably estimable, such commitments have not been included in the table above.

Off-Balance Sheet Activities

As of December 31, 2008, we had no material off-balance sheet arrangements other than the lease obligations and collaboration payments discussed above.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur operating losses for the next 12 months and to make capital expenditures to keep pace with the expansion of our research and development programs and to scale our commercial operations. However, we cannot provide assurance as to when, if ever, we will achieve profitability. We expect to spend approximately $5.0 million over the next 12 months for planned laboratory equipment and other capital expenditures in order to support the growth of our business. It may take years to move any one of a number of product candidates in research through development and validation to commercialization. We expect that our cash and cash equivalents will be used to fund working capital and for capital expenditures and other general corporate purposes, such as licensing technology rights, partnering arrangements for our tests outside the U.S., establishing direct sales capabilities outside of the U.S. or reduction of debt obligations. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the progress of our product development, regulatory requirements, commercialization efforts, the amount of cash used by operations, progress in reimbursement and the pace of international expansion.

We currently anticipate that our cash, cash equivalents and short-term investments, together with collections from Onco*type* DX, will be sufficient to fund our operations and facilities expansion plans for at least the next 12 months. We cannot be certain that our development of future products will be successful or that we will be able to raise sufficient additional funds to see these programs through to a successful commercial product.

Our future funding requirements will depend on many factors, including the following:

- the rate of progress in establishing reimbursement arrangements with third-party payors;
- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;
- the rate of progress and cost of research and development activities associated with expansion of Onco*type* DX for breast cancer;
- the rate of progress and cost of research and development activities associated with products in the early development and validation phase focused on cancers other than breast cancer;
- the cost of acquiring or achieving access to tissue samples and technologies;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the effect of competing technological and market developments;

costs related to international expansion;

the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products or operations; and

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the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter.

Until we can generate a sufficient amount of product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The issuance of equity securities may result in dilution to stockholders, or may provide for rights, preferences or privileges senior to those of our holders of common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. We do not know whether additional funding will be available on acceptable terms, if at all. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. These events have generally made equity and debt financing difficult to obtain. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our product or market development programs, which would lower the economic value of those programs to our company.

Recent Accounting Pronouncements

In February 2008, Financial Accounting Standards Board, or FASB issued FASB Staff Position 157-2*, Effective Date of FASB Statement No. 157(SFAS 157)*, or FSP 157-2. FSP 157-2 delays the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. We have elected a partial deferral of SFAS 157 under the provisions of FSP 157-2. We do not expect the application of SFAS 157 to our non-financial assets and non-financial liabilities to have a material impact on our financial condition or results of operations.

In November 2007, FASB ratified Emerging Issues Task Force Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1, which defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in a collaborative arrangement and third parties. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-01 to have a material impact on our financial condition or results of operations.

ITEM 7A. ***Quantitative and Qualitative Disclosures About Market Risk.***

Our exposure to market risk is confined to our cash equivalents and marketable securities. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our investment policy provides for investments in short-term, low-risk, investment-grade debt instruments. Our investments in marketable securities, which are comprised primarily of money market funds, obligations of U.S. Government agencies and government-sponsored entities, high-grade corporate bonds and commercial paper, are subject to default, changes in credit rating and changes in market value. Due to recent financial and economic conditions, similar investments have experienced losses in value and liquidity constraints which differ from historical patterns. These investments are also subject to interest rate risk and will decrease in value if market rate interest rates increase.

Our cash, cash equivalents and marketable securities, totaling $56.7 million at December 31, 2008, did not include any auction preferred stock, auction rate securities or mortgage-backed investments. We currently do not hedge interest rate exposure, and we do not have any foreign currency or other derivative financial instruments. The securities in our investment portfolio are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. To date, we have not experienced a loss of principal on any of our investments. Although we currently expect that our ability to access or liquidate these investments as needed to support our business activities will continue, we cannot ensure that this will not change. We believe that, if market interest rates were to change immediately and uniformly by 10% from levels at December 31, 2008, the impact on the fair value of these securities or our cash flows or income would not be material.

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ITEM 8. ***Financial Statements and Supplementary Data.***

Genomic Health, Inc.

Index to consolidated financial statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Genomic Health, Inc.

We have audited the accompanying consolidated balance sheets of Genomic Health, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2008. Our audits also included the financial statement schedule included under Item 15(a)(2). These consolidated financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genomic Health, Inc. at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Genomic Health, Inc. s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 12, 2009

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GENOMIC HEALTH, INC.

Consolidated Balance Sheets

	December 31, 2008	2007
	(In thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,171	$ 39,164
Short-term investments	45,499	29,196
Accounts receivable (net of allowance for doubtful accounts; 2008 $881, 2007 $133)	8,807	5,089
Prepaid expenses and other current assets	4,781	3,105
Total current assets	70,258	76,554
Property and equipment, net	15,562	10,412
Restricted cash	500	500
Other assets	369	463
Total assets	$ 86,689	$ 87,929
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,898	$ 1,966
Accrued compensation	4,157	3,672
Accrued license fees	2,553	1,798
Accrued expenses and other current liabilities	4,398	1,948
Notes payable current portion	1,814	2,687
Deferred revenues current portion	2,381	337
Lease incentive obligations current portion	364	198
Total current liabilities	17,565	12,606
Notes payable long-term portion	225	2,039
Deferred revenues long-term portion	1,417	671
Lease incentive obligations long-term portion	789	629
Other liabilities	518	818
Commitments (Note 8)		
Stockholders equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2008 and 2007	2	2

Common stock, $0.0001 par value; 100,000,000 shares authorized, 28,461,327 and 28,181,859 shares issued and outstanding at December 31, 2008 and 2007 respectively		
Additional paid-in capital	234,412	223,507
Accumulated other comprehensive income	245	52
Accumulated deficit	(168,484)	(152,395)
Total stockholders equity	66,175	71,166
Total liabilities and stockholders equity	$ 86,689	$ 87,929

See accompanying notes.

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GENOMIC HEALTH, INC.

Consolidated Statements of Operations

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except share and per share amounts)		
Revenues:			
Product revenues	$ 108,658	$ 62,745	$ 27,006
Contract revenues	1,921	1,282	2,168
Total revenues	110,579	64,027	29,174
Operating expenses:			
Cost of product revenues	27,185	17,331	9,908
Research and development	28,624	22,053	12,841
Selling and marketing	46,668	36,456	24,625
General and administrative	25,617	17,849	12,765
Total operating expenses	128,094	93,689	60,139
Loss from operations	(17,515)	(29,662)	(30,965)
Interest and other income	1,751	3,048	2,491
Interest expense	(386)	(678)	(446)
Loss before income tax benefit	(16,150)	(27,292)	(28,920)
Income tax benefit	61		
Net loss	$ (16,089)	$ (27,292)	$ (28,920)
Basic and diluted net loss per share	$ (0.57)	$ (1.02)	$ (1.18)
Shares used in computing basic and diluted net loss per share	28,297,705	26,759,798	24,508,845

See accompanying notes.

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GENOMIC HEALTH, INC.

Consolidated Statements of Stockholders Equity

	Common Stock		Additional Paid-In	Deferred Stock-Based	Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Capital	Compensation	Income (Loss)	Deficit	Equity
	(In thousands, except share and per share amounts)						
Balance at December 31, 2005	**24,470,981**	**$ 2**	**$ 167,053**	**$ (3,297)**	**$ (58)**	**$ (96,183)**	**$ 67,517**
Deferred stock-based compensation reclassified upon adoption of SFAS 123R on January 1, 2006			(3,297)	3,297			
Issuance of common stock to employees upon exercise of stock options for cash	74,826		173				173
Issuance of common stock to consultants upon exercise of stock options for cash	2,253		6				6
Stock-based compensation expense related to employee stock options			2,904				2,904
Stock-based compensation expense related to consultant stock options			83				83
Comprehensive loss:							
Net loss						(28,920)	(28,920)
Change in unrealized gain on investments					66		66
Comprehensive loss							(28,854)
Balance at December 31, 2006	**24,548,060**	**2**	**166,922**		**8**	**(125,103)**	**41,829**
Issuance of common stock for cash, net of issuance costs	3,450,000		49,668				49,668
Issuance of common stock to employees upon	174,287		552				552

exercise of stock options for cash							
Issuance of common stock to consultants upon exercise of stock options for cash	9,512		15				15
Stock-based compensation expense related to employee stock options			6,285				6,285
Stock-based compensation expense related to consultant stock options			65				65
Comprehensive loss:							
Net loss						(27,292)	(27,292)
Change in unrealized gain on investments					44		44
Comprehensive loss							(27,248)
Balance at December 31, 2007	**28,181,859**	**2**	**223,507**		**52**	**(152,395)**	**71,166**
Issuance of common stock to employees upon exercise of stock options for cash	245,035		1,425				1,425
Issuance of common stock to consultants upon exercise of stock options for cash	34,433		254				254
Stock-based compensation expense related to employee stock options			9,138				9,138
Stock-based compensation expense related to consultant stock options			88				88
Comprehensive loss:							
Net loss						(16,089)	(16,089)
Change in unrealized gain on investments					193		193
Comprehensive loss							(15,896)
Balance at December 31, 2008	**28,461,327**	**$ 2**	**$ 234,412**	**$**	**$ 245**	**$ (168,484)**	**$ 66,175**

See accompanying notes.

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GENOMIC HEALTH, INC.

Consolidated Statements of Cash Flows

	2008	December 31, 2007	2006
		(In thousands)	
Operating activities			
Net loss	$ (16,089)	$ (27,292)	$ (28,920)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,012	3,995	2,629
Employee stock-based compensation	9,138	6,285	2,904
Non-employee stock-based compensation	88	65	83
Gain on disposal of property and equipment			(3)
Changes in assets and liabilities:			
Accounts receivable	(3,718)	(3,227)	(1,548)
Employee note receivable			37
Prepaid expenses and other assets	(1,687)	(1,647)	(228)
Accounts payable	(68)	(557)	1,130
Accrued expenses and other liabilities	2,905	1,608	933
Accrued compensation	485	1,804	913
Deferred revenues	2,790	161	609
Lease incentive obligations	326	99	728
Net cash used in operating activities	(818)	(18,706)	(20,733)
Investing activities			
Purchase of property and equipment	(10,057)	(4,881)	(8,424)
Purchase of short-term investments	(112,109)	(66,021)	(40,002)
Maturities of short-term investments	95,999	66,158	61,467
Net cash provided by (used in) investing activities	(26,167)	(4,744)	13,041
Financing activities			
Proceeds from notes payable			4,912
Principal payments of notes payable	(2,687)	(2,547)	(1,312)
Proceeds from issuance of common stock upon exercise of stock options	1,679	565	179
Net proceeds from issuance of common stock in public offering		49,670	
Net cash provided by (used in) financing activities	(1,008)	47,688	3,779
Net increase (decrease) in cash and cash equivalents	(27,993)	24,238	(3,913)
Cash and cash equivalents at the beginning of period	39,164	14,926	18,839
Cash and cash equivalents at the end of period	$ 11,171	$ 39,164	$ 14,926

Supplemental disclosure of cash flow information			
Cash paid for interest	$ 386	$ 678	$ 446

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2008

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. The Company was incorporated in Delaware in August 2000. The Company s first test, Onco*type* DX, was launched in 2004 and is used for early-stage breast cancer patients to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit. The Company has incurred significant losses and expects to incur additional losses for at least the next year as commercial and development efforts continue. However, the Company cannot provide assurance as to when, if ever, it will achieve profitability.

Principles of Consolidation

The consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiary. The Company has one wholly-owned subsidiary, Onco*type* Laboratories, Inc., which was established in 2003 and is inactive.

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of financial statements in conformity with generally accepted accounting principles requires management to make judgments, assumptions and estimates that affect the amounts reported in the Company s consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Certain reclassifications of prior period amounts have been made to the Company s consolidated financial statements to conform to the current period presentation.

Cash Equivalents and Short-term Investments

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

The Company invests in marketable securities, primarily money market securities, obligations of U.S. Government agencies and government-sponsored entities, corporate bonds and commercial paper. The Company considers all investments with a maturity date less than one year as of the balance sheet date to be short-term investments. These securities are carried at estimated fair value with unrealized gains and losses included in stockholders equity. Those investments with a maturity date greater than one year as of the balance sheet date are considered to be long-term investments. As of December 31, 2008, all investments were classified as available for sale.

Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are reported in other income or expense. When securities are sold, any associated unrealized gain or loss recorded as a separate component of stockholders equity is reclassified out of stockholders equity on a

specific-identification basis and recorded in earnings for the period.

Fair Value of Financial Instruments

The carrying amounts of certain of the Company s financial instruments, including cash and cash equivalents, short-term investments, trade receivables and accounts payable, approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for loans and capital lease obligations with similar terms, the carrying value of the Company s debt obligations approximates fair value.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 applies whenever standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances.

The Company adopted SFAS 157 as of January 1, 2008 for financial assets and liabilities measured at fair value. There was no financial statement impact as a result of adoption. The Company will adopt SFAS 157 for non-financial assets and liabilities as of January 1, 2009. See Note 3 for more information.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, issued debt and other financial assets and liabilities. SFAS 159 is effective for fiscal years beginning after November 15, 2007.

The Company adopted SFAS 159 effective January 1, 2008 and did not elect fair value as an alternative measurement for any financial instruments not previously carried at fair value.

In October 2008, FASB issued Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP 157-3) which clarifies the application of SFAS 157 in an inactive market and illustrates how an entity would determine fair value when the market for a financial asset is not active. The Company adopted FSP 157-3 as of September 30, 2008. There was no financial impact as a result of adoption.

Concentration of Risk

Cash equivalents, short-term investments and accounts receivable are financial instruments which potentially subject the Company to concentrations of credit risk. The Company invests in money market securities through a major U.S. bank and is exposed to credit risk in the event of default by the financial institution to the extent of amounts recorded on the consolidated balance sheets. The Company invests in short-term, investment-grade debt instruments and by policy limits the amount in any one type of investment, except for securities issued or guaranteed by the U.S. Government. Through December 31, 2008, no material losses had been incurred.

As of December 31, 2008, all of the Company s product revenues have been derived from sales of one product, the Onco*type* DX test. Substantially all of the Company s tests to date have been delivered to physicians in the United States. All Onco*type* DX assays are processed in the Company s clinical reference laboratory facility in Redwood City, California. One third-party payor accounted for approximately 22%, 23% and 47% of the Company s product revenues for the years ended December 31, 2008, 2007 and 2006, respectively. This payor represented 42% and 55% of the Company s net accounts receivable balance as of December 31, 2008 and 2007, respectively. Another third-party payor accounted for approximately 9%, 13% and 5% of the Company s product revenues in 2008, 2007 and 2006, respectively. This payor represented 14% and 10% of the Company s accounts receivable balance as of December 31, 2008 and 2007, respectively.

Allowance for Doubtful Accounts

The Company accrues an allowance for doubtful accounts against its accounts receivable consistent with historical payment experience. Bad debt expense is included in general and administrative expense on the Company s consolidated statements of operations. Accounts receivable are written off against the allowance when the appeals process is exhausted, when an unfavorable coverage decision is received or when there is other substantive evidence that the account will not be paid. As of December 31, 2008 and 2007, the Company s allowance for doubtful accounts was $881,000 and $133,000, respectively. Write-offs for doubtful accounts of $595,000 and $261,000 were recorded against the allowance during the years ended December 31, 2008 and 2007,

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

respectively. Bad debt expense was $1.3 million, ($115,000) and $510,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Changes in the Company s estimate of allowance for doubtful accounts resulted in the reduction of bad debt expense for the year ended December 31, 2007.

Property and Equipment

Property and equipment are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized using the straight-line method over the estimated useful lives of the assets or the remaining term of the lease, whichever is shorter.

Internal-Use Software

The Company accounts for software developed or obtained for internal use in accordance with Statement of Position 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use.* The statement requires capitalization of certain costs incurred in the development of internal-use software, including external direct material and service costs and employee payroll and payroll-related costs. Capitalized internal-use software costs, which are included in property and equipment, are generally depreciated over three years.

Leases

The Company enters into lease agreements for its laboratory and office facilities. These leases are classified as operating leases. Rent expense is recognized on a straight-line basis over the term of the lease. Incentives granted under the Company s facilities leases, including allowances to fund leasehold improvements and rent holidays, are capitalized and are recognized as reductions to rental expense on a straight-line basis over the term of the lease.

Intangible Assets

Intangible assets with finite useful lives are recorded at cost, less accumulated amortization. Amortization is recognized over the estimated useful lives of the assets.

Impairment of Long-lived Assets

The Company reviews long-lived assets, which include property and equipment and intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. An impairment loss would be recognized when estimated discounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows. There were no impairment losses for the years ended December 31, 2008, 2007 and 2006.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at

the Company s request in such capacity. The term of the indemnification period is for the officer s or director s lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2008 and 2007.

Income Taxes

The Company uses the liability method for income taxes, whereby deferred income taxes are provided on items recognized for financial reporting purposes over different periods than for income tax purposes. Valuation allowances are provided when the expected realization of tax assets does not meet a more-likely-than-not criterion.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company adopted FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), as of January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FASB Staff Position FIN 48-1 (FSP FIN 48-1), which provides guidance on determining whether a tax position is effectively settled for purposes of recognizing previously unrecognized tax benefits, was issued in May 2007 and is effective upon the Company s initial adoption of FIN 48. The adoption of FIN 48 and FSP FIN 48-1 had no impact on the Company s financial condition, results of operations or cash flows. See Note 12, Income Taxes, for additional FIN 48 disclosures.

Comprehensive Gain or Loss

The Company displays comprehensive gain or loss and its components within its consolidated statements of stockholders equity. Other comprehensive gain or loss consists entirely of unrealized gains and losses on available-for-sale investments.

Revenue Recognition

The Company derives its revenues from product sales and contract research arrangements. The Company operates in one industry segment. Product revenues are derived solely from the sale of the Onco*type* DX test for breast cancer. The Company generally bills third-party payors for Onco*type* DX upon generation and delivery of a Recurrence Score report to the physician. As such, the Company takes assignment of benefits and the risk of collection with the third-party payor. The Company usually bills the patient directly for amounts owed after multiple requests for payment have been denied or only partially paid by the insurance carrier. As a relatively new test, Onco*type* DX may be considered investigational by some payors and therefore not covered under their reimbursement policies. Consequently, the Company pursues case-by-case reimbursement where policies are not in place or payment history has not been established.

The Company s product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. Criterion (1) is satisfied when the Company has an agreement or contract with the payor in place, or when the payor has issued a policy addressing reimbursement for the Onco*type* DX test. Criterion (2) is satisfied when the Company performs the test and generates and delivers a Recurrence Score report to the physician. Determination of criteria (3) and (4) is based on management s judgments regarding whether the fee charged for products or services delivered is fixed or determinable, contractual agreements entered into, and the collectibility of those fees under any contract or agreement. When evaluating collectibility, the Company considers whether it has sufficient history to reliably estimate a payor s individual payment patterns. Based upon at least several months of payment history, the Company reviews the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the contracted payment amount. To the extent all criteria set forth above are not met when test results are delivered, product revenues are recognized when cash is received from the payor.

Prior to 2008, product revenues had largely been recognized on a cash basis because the Company had a limited number of contracts or agreements with third-party payors and limited collections experience. The Company recognizes a portion of its product revenue from third-party payors, including some private payors and Medicare, on an accrual basis prospectively when the criteria described in the preceding paragraph are satisfied. For the year ended December 31, 2008, approximately half of total product revenue recognized was recorded on an accrual basis.

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies. The specific methodology for revenue recognition is determined on a case-by-case basis according to

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the facts and circumstances applicable to a given contract. Under certain contracts, the Company s input, measured in terms of full-time equivalent level of effort or running a set of assays through its clinical reference laboratory under a contractual protocol, triggers payment obligations, and revenues are recognized as costs are incurred or assays are processed. Certain contracts have payments that are triggered as milestones are completed, such as completion of a successful set of experiments. Milestones are assessed on an individual basis and revenue is recognized when these milestones are achieved, as evidenced by acknowledgment from collaborators, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (2) the milestone payment is non-refundable. Where separate milestones do not meet these criteria, the Company typically defaults to a performance-based model, such as revenue recognition following delivery of effort as compared to an estimate of total expected effort.

Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met.

Stock-based Compensation

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment* (SFAS 123R). SFAS 123R addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. SFAS 123R eliminates the ability to account for stock-based payment transactions using the intrinsic value method under Accounting Principles Board Opinion No. 25 (APB 25), and instead requires that such transactions be accounted for using a fair-value based method. The application of SFAS 123R requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Company uses the Black-Scholes valuation method, which requires the use of estimates such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value stock-based compensation, and recognizes stock-based compensation expense on a straight-line basis.

The Company elected the modified prospective transition method as permitted under SFAS 123R, which requires that stock-based compensation expense be recorded for all new and unvested stock options that are ultimately expected to vest as the requisite service is rendered beginning on January 1, 2006. Stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted on or after January 1, 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of December 31, 2008, total unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was $18.2 million. The Company expects to recognize this expense over a weighted-average period of 46 months.

Equity instruments granted to non-employees are valued using the Black-Scholes method and accounted for as prescribed by SFAS 123R and 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* (EITF 96-18), and will be subject to periodic revaluation over their vesting terms.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards* (FSP 123R-3). The Company elected to adopt the alternative transition method provided in FSP 123R-3 for calculating the tax effects (if any) of stock-based compensation expense pursuant to SFAS 123R. The alternative transition method includes simplified methods to

establish the beginning balance of the additional paid-in capital pool, or APIC pool, related to the tax effects of employee stock-based compensation (if any), and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects (if any) of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123R.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

401(k) Plan

Substantially all of the Company s employees are covered by its defined contribution plan qualified under Section 401(k) of the Internal Revenue Code. On January 1, 2007, the Company began dollar for dollar matching of employee contributions up to a maximum of $1,000 for each employee per year. The match is funded concurrently with a participant s semi-monthly contributions to the 401(k) Plan. The Company recorded expense of $320,000 and $246,000 for the years ended December 31, 2008 and 2007 for its contributions under the Plan. There were no employer match contributions to the 401(k) Plan for the year ended December 31, 2006.

Cost of Product Revenues

Cost of product revenues includes the cost of materials, direct labor, equipment and infrastructure expenses associated with processing tissue samples (including histopathology, anatomical pathology, paraffin extraction, RT-PCR and quality control analyses), shipping charges to transport tissue samples and license fees. Infrastructure expenses include allocated facility occupancy and information technology costs. Costs associated with performing the Company s tests are recorded as tests are processed. Costs recorded for tissue sample processing and shipping charges represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. License fees for royalties due on product revenues and contractual obligations are recorded in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations.

Research and Development

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: salaries and benefits, allocated overhead and facility occupancy costs, contract services, reagents and laboratory supplies, and costs to acquire in-process research and development projects and technologies that have no alternative future use. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies. Research and development costs are expensed as incurred.

The Company enters into collaboration and clinical trial agreements with clinical collaborators and records these costs as research and development expenses. The Company records accruals for estimated study costs comprised of work performed by its collaborators under contract terms.

In June 2007, FASB ratified EITF Issue No. 07-3, *Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

The Company adopted EITF 07-03 effective January 1, 2008 for arrangements that were entered into after that date. Prior to January 1, 2008, the Company recognized non-refundable advance payments for goods and services to be used for future research and development activities as an expense when payments were made. As a result of the adoption of EITF 07-3, the Company s research and development expenses decreased by $258,000 and its net loss per share decreased by $0.01 for the year ended December 31, 2008. The Company expects to recognize these deferred and capitalized amounts as expense in future periods as the related services are delivered.

Recently Issued Accounting Pronouncements

In February 2008, FASB issued FASB Staff Position 157-2*, Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 delays the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. The Company has elected a partial

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

deferral of SFAS 157 under the provisions of FSP 157-2. The Company does not expect the application of SFAS 157 to its non-financial assets and non-financial liabilities to have a material impact on its financial condition or results of operations when the standard is applied

In November 2007, FASB ratified EITF No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in a collaborative arrangement and third parties. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. The Company does not expect the adoption of EITF 07-01 to have a material impact on its financial condition or results of operations.

Note 2. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss for the period by the weighted-average number of common shares outstanding for the period without consideration for potential common shares. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period and dilutive potential common shares for the period determined using the treasury-stock method. For the purposes of this calculation, options to purchase common stock are considered to be potential common shares and are not included in the calculation of diluted net loss per share because their effect is anti-dilutive.

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except share and per share data)		
Net loss	$ (16,089)	$ (27,292)	$ (28,920)
Weighted-average net common shares outstanding for basic and diluted loss per common share	28,297,705	26,759,798	24,508,845
Basic and diluted net loss per share	$ (0.57)	$ (1.02)	$ (1.18)
Outstanding dilutive securities not included in diluted net loss per share calculation (at end of period):			
Options to purchase common stock	4,665,037	3,919,720	2,940,803

Note 3. Fair Value Measurements

On January 1, 2008, the Company adopted the provisions of SFAS 157 for its financial assets and liabilities. As permitted by FSP 157-2, the Company elected to defer the adoption of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in its financial statements on a recurring basis (at least annually), until January 1, 2009. SFAS 157 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. SFAS 157 defines fair value as

the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. SFAS 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

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

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

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The following table sets forth the Company s financial instruments that were measured at fair value on a recurring basis at December 31, 2008 by level within the fair value hierarchy. The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at December 31, 2008. As required by SFAS 157, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability:

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2008
		(In thousands)		
As of December 31, 2008:				
Assets				
Money market deposits	$ 5,926	$	$	$ 5,926
U.S. Treasury securities	1,004			1,004
Debt securities of U.S. government-sponsored agencies		37,350		37,350
Commercial paper		8,146		8,146
Corporate bonds		1,000		1,000

Note 4. Commercial Technology Licensing Agreements

The Company is a party to various agreements under which it licenses technology on a nonexclusive basis in the field of human diagnostics. Access to these licenses enables the Company to process its laboratory tests for Onco*type* DX. While certain agreements contain provisions for fixed annual payments, license fees are generally calculated as a percentage of product revenues, with rates that vary by agreement and may be tiered, and payments that may be capped at annual minimum or maximum amounts. The Company recognized costs recorded under these agreements for the years ended December 31, 2008, 2007 and 2006 of $7.7 million, $4.9 million and $2.2 million, respectively, which were included in cost of product revenues.

Note 5. Short-term Investments

The following tables illustrate the Company s available-for-sale securities as of the dates indicated:

	December 31, 2008			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Debt securities of U.S. government-sponsored entities	$ 37,144	$ 209	$ (3)	$ 37,350
Corporate debt securities	8,110	42	(3)	8,149
Total	$ 45,254	$ 251	$ (6)	$ 45,499

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	December 31, 2007			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Debt securities of U.S. government-sponsored entities	$ 2,848	$ 1	$	$ 2,849
Corporate debt securities	26,296	53	(2)	26,347
Total	$ 29,144	$ 54	$ (2)	$ 29,196

The Company had no realized gains or losses on its available-for-sale securities for the years ended December 31, 2008, 2007 and 2006, respectively.

The amortized cost and estimated fair value of available-for-sale securities by contractual maturity at December 31, 2008 was as follows:

	December 31, 2008	
	Cost	Market Value
	(In thousands)	
Due in one year or less	$ 45,254	$ 45,499

Note 6. Property and Equipment

The following table summarizes the Company s property and equipment as of the dates indicated:

	December 31,	
	2008	2007
	(In thousands)	
Laboratory equipment	$ 12,236	$ 9,881
Computer equipment and internal-use software	2,931	1,520
Furniture and fixtures	2,357	1,736
Leasehold improvements	12,489	7,297
Construction in progress		276
	30,013	20,710
Less accumulated depreciation and amortization	(14,451)	(10,298)
Total	$ 15,562	$ 10,412

For the years ended December 31, 2008, 2007 and 2006, the Company recorded depreciation and amortization expense of $4.9 million, $3.9 million and $2.6 million, respectively.

Note 7. Accrued Expenses and Other Liabilities

The following table summarizes the Company s accrued expenses and other current liabilities as of the dates indicated:

	December 31,	
	2008	2007
	(In thousands)	
Accrued expenses	$ 2,022	$ 1,105
Accrued refunds	1,359	60
Accrued professional and other service fees	916	698
Other current liabilities	101	85
Total	$ 4,398	$ 1,948

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accrued refunds includes overpayments due to third-party payors. Accrued professional and other service fees includes third-party billing and collections costs, legal expenses, accounting and audit fees and investor relations expenses.

Note 8. Commitments

Notes Payable

In March 2005, the Company entered into an arrangement to finance the acquisition of laboratory and office equipment, computer hardware and software and leasehold improvements. In connection with this arrangement, the Company granted the lender a security interest in the assets purchased with the borrowed amounts. Beginning in April 2006, the Company could prepay all, but not part of, the amounts outstanding under the arrangement so long as the Company also paid a 6% premium on the outstanding principal balance. This premium was reduced to 5% in April 2007 and further reduced to 4% in April 2008. As of December 31, 2008, the outstanding notes payable principal balance under this arrangement was $2.0 million at annual interest rates ranging from 10.23% to 11.30%, depending on the applicable note. According to the terms of the arrangement, the Company is required to notify the lender if there is a material adverse change in its financial condition, business or operations. The Company believes it has complied with all the material covenants of the financing arrangement during the years ended December 31, 2008, 2007 and 2006.

As of December 31, 2008, the Company s aggregate commitments under its financing arrangement were as follows:

	Annual Payment Amounts (In thousands)
Years Ending December 31,	
2009	$ 1,934
2010	238
Total minimum payments	2,172
Less: interest portion	(133)
Present value of net minimum payments	2,039
Less: current portion of obligations	(1,814)
Long-term obligations	$ 225

Lease Obligations

In September 2005, the Company entered into a non-cancelable lease directly with the facility owner for 48,000 square feet of laboratory and office space that the Company currently occupies in Redwood City, California. The lease expires in February 2012 and includes lease incentive obligations of $834,000 that are being amortized on a straight-line basis over the life of the lease. In connection with this lease, the Company was required to secure a $500,000 letter of credit, which is classified as restricted cash on the consolidated balance sheets.

In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space in a nearby location. The lease expires in February 2012 and includes lease incentive obligations totaling $283,000 that are being amortized on a straight-line basis over the life of the lease. In connection with this lease, the Company paid a $151,000 cash security deposit, which is included in other assets on the consolidated balance sheets.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Rent expense under all operating leases amounted to $1.1 million, $1.2 million and $810,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

Future non-cancelable commitments under these operating leases at December 31, 2008 were as follows (in thousands):

	Annual Payment Amounts (In thousands)
Years Ending December 31,	
2009	$ 1,520
2010	1,634
2011	1,723
2012	290
Total minimum payments	$ 5,167

Clinical Collaborator Costs

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. The Company recorded collaboration expenses of $1.4 million, $1.3 million and $1.5 million for the years ended December 31, 2008, 2007 and 2006, respectively, relating to services provided in connection with these agreements. In addition to these expenses, certain agreements contain provisions for royalties from inventions resulting from these collaborations. The Company has certain options and rights relating to joint inventions arising out of the collaborations.

At December 31, 2008, future fixed annual payments, exclusive of royalty payments, relating to the launch and commercialization of Onco*type* DX totaled $1.4 million and are payable as follows:

	Annual Payments (In thousands)
Payment Due:	
January 2009	$ 475
January 2010	475
January 2011	475
Total payments	$ 1,425

These payments are recorded in cost of product revenues as license fees. Expense is recorded ratably over the year before the relevant payment is made. If at any time the Company discontinues the sale of commercial products or services resulting from the collaboration, no future annual payments will be payable and the Company will have no further obligation under the agreement. If the Company s cash balance is less than $5.0 million on the due date of any of the annual payments, the Company may be able to defer any current annual payment due for a period of up to 12 months.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Capital Stock

Common Stock

As of December 31, 2008, the Company had 28,461,327 shares of common stock outstanding. Shares of common stock reserved for future issuance as of December 31, 2008 were as follows:

Shares to be issued upon exercise of outstanding stock options	4,665,037
Shares available for future stock option grants	1,055,472
Shares of common stock reserved for future issuance	5,720,509

Public Offering of Common Stock

On May 25, 2007, the Company closed an underwritten public offering of 3,450,000 shares of common stock at a price to the public of $15.50 per share pursuant to the Company s shelf registration statement on Form S-3. Net proceeds from the offering, after deducting the underwriting discounts and offering expenses, were $49.7 million. Entities affiliated with Julian Baker, an outside director and a principal stockholder of the Company, purchased 1,000,000 shares of the Company s common stock in this offering. As of December 31, 2008, the Company had approximately $46.5 million of securities available for sale under a shelf registration statement. See Note 11 for further information on related parties.

Note 10. Stock-based Compensation

2005 Stock Incentive Plan

On September 8, 2005, the Board of Directors approved the 2005 Stock Incentive Plan (the 2005 Plan), which was later approved by the Company s stockholders. The Company has reserved 5,000,000 shares of the Company s common stock for issuance under the 2005 Plan. The 2005 Plan became effective upon the closing of the Company s initial public offering on October 4, 2005. Pursuant to the 2005 Plan, stock options, restricted shares, stock units, and stock appreciation rights may be granted to employees, consultants, and outside directors of the Company. Options granted may be either incentive stock options or nonstatutory stock options.

Stock options are governed by stock option agreements between the Company and recipients of stock options. Incentive stock options may be granted under the 2005 Plan at an exercise price of not less than 100% of the fair market value of the common stock on the date of grant, determined by the Compensation Committee of the Board of Directors. Nonstatutory stock options may be granted under the 2005 Plan at an exercise price of not less than 80% of the fair market value of the common stock on the date of grant, determined by the Compensation Committee of the Board of Directors. Options become exercisable and expire as determined by the Compensation Committee, provided that the term of incentive stock options may not exceed 10 years from the date of grant. Stock option agreements may provide for accelerated exercisability in the event of an optionee s death, disability, or retirement or other events.

Under the 2005 Plan, each outside director who joins the board after the effective date of the 2005 Plan will receive an automatic nonstatutory stock option grant that vests at a rate of 25% at the end of the first year, with the remaining balance vesting monthly over the next three years. On the first business day following the annual meeting of the Company s stockholders, each outside director who is continuing board service and who was not initially elected to the board at the annual meeting will receive an additional nonstatutory stock option grant, which will vest in full on the first anniversary of the date of grant or, if earlier, immediately prior to the next annual meeting of the Company s stockholders. Nonstatutory stock options granted to outside directors must have an exercise price equal to 100% of the fair market value of the common stock on the date of grant. Nonstatutory stock options terminate on the earlier of the day before the tenth anniversary of the date of grant or the date twelve months after termination of the outside director s service as a member of the board of directors.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Restricted shares, stock appreciation rights, and stock units granted under the 2005 Plan are governed by restricted stock agreements, SAR agreements, and stock unit agreements between the Company and recipients of the awards. Terms of the agreements are determined by the Compensation Committee.

2001 Stock Incentive Plan

The Company s 2001 Stock Incentive Plan (the 2001 Plan) was terminated upon completion of the Company s initial public offering on October 4, 2005. No shares of common stock are available under the 2001 Plan other than to satisfy exercises of stock options granted under the 2001 Plan prior to its termination. Under the 2001 Plan, incentive stock options and nonstatutory stock options were granted to employees, officers, and directors of, or consultants to, the Company and its affiliates. Options granted under the 2001 Plan expire no later than 10 years from the date of grant.

Employee Stock-Based Compensation Expense

Employee stock-based compensation expense for the years ended December 31, 2008, 2007 and 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Employee stock-based compensation expense includes expense related to options granted to outside directors of the Company. The Company recorded employee stock-based compensation expense of $9.1 million, $6.3 million and $2.9 million for the years ended December 31, 2008, 2007 and 2006, respectively. The following table presents the impact of employee stock-based compensation expense on selected statements of operations line items for the years ended December 31, 2008, 2007 and 2006:

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Cost of product revenues	$ 491	$ 375	$ 167
Research and development	2,913	1,882	821
Selling and marketing	2,622	1,876	779
General and administrative	3,112	2,152	1,137
Total	$ 9,138	$ 6,285	$ 2,904

Employee stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted on or after January 1, 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of December 31, 2008, total unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was $18.2 million. The Company expects to recognize this expense over a weighted-average period of 46 months.

Valuation Assumptions

The employee stock-based compensation expense recognized under SFAS 123R was determined using the Black-Scholes option valuation model. Option valuation models require the input of highly subjective assumptions that can vary over time. As of January 2008, the Company s assumptions regarding expected volatility are based on the historical volatility of the Company s common stock. Prior to January 2008, the Company s assumptions regarding expected volatility were based primarily on comparable peer data because the Company s common stock had been publicly traded for less than two years. The expected life of options granted is estimated based on historical option exercise data and assumptions related to unsettled options. The risk-free interest rate is estimated using published rates for U.S. Treasury securities with a remaining term approximating the expected life of the options granted. The Company uses a dividend yield of zero as it has never paid cash dividends and does not

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

anticipate paying cash dividends in the foreseeable future. The weighted-average fair values and assumptions used in calculating such values during each fiscal year are as follows:

	Year Ended December 31,		
	2008	2007	2006
Expected volatility	58%	61%	68%
Risk-free interest rate	1.98%	3.93%	4.76%
Expected life of options in years	5.8	5.8	5.5
Weighted-average fair value	$ 9.79	$ 12.77	$ 10.27

Stock Options Granted to Non-employees

The Company grants stock options to consultants from time to time in exchange for services performed for the Company. During the years ended December 31, 2008, 2007 and 2006, the Company granted options to purchase 14,400, 9,600 and 2,850 shares, respectively, to consultants. The fair value of these option grants was determined using the Black-Scholes option pricing model and accounted for as prescribed by SFAS 123R and EITF 96-18. In general, the options vest over the contractual periods of the respective consulting arrangement and, therefore, the Company revalues the options periodically and records additional compensation expense related to these options over the remaining vesting periods. During the years ended December 31, 2008, 2007 and 2006, stock-based compensation expense related to these options was $88,000, $65,000 and $83,000, respectively.

Stock Option Activity

The following is a summary of option activity for the years ended December 31, 2008, 2007 and 2006:

		Outstanding Options	
	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 2005	4,290,631	2,021,276	$ 4.75
Options granted	(1,043,705)	1,043,705	$ 16.61
Options exercised		(77,079)	$ 2.36
2001 Plan shares expired	(35,589)		
Options cancelled	71,499	(71,499)	$ 5.94
Balance at December 31, 2006	3,282,836	2,916,403	$ 9.04
Options granted	(1,287,917)	1,287,917	$ 21.71
Options exercised		(183,799)	$ 3.07
2001 Plan shares expired	(11,259)		
Options cancelled	100,801	(100,801)	$ 15.09

Balance at December 31, 2007	2,084,461	3,919,720	$	13.33
Options granted	(1,191,380)	1,191,380	$	17.96
Options exercised		(279,468)	$	6.01
2001 Plan shares expired	(4,204)			
Options cancelled	166,595	(166,595)	$	18.61
Balance at December 31, 2008	1,055,472	4,665,037	$	14.76

The intrinsic value of stock options exercised during 2008, 2007 and 2006 was $4.1 million, $2.9 million and $948,000, respectively. The estimated fair value of options vesting in 2008, 2007 and 2006 was $10.1 million, $5.6 million and $2.7 million, respectively.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes information concerning outstanding and exercisable options under the 2001 and 2005 Plans as of December 31, 2008:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Number Outstanding	Weighted-Average Years Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$ 0.58 - $ 1.33	387,728	4.89	$ 1.15	387,728	$ 1.15
$ 2.88 - $ 2.88	426,646	5.96	$ 2.88	416,978	$ 2.88
$ 9.39 - $ 9.39	537,750	6.84	$ 9.39	395,518	$ 9.39
$ 9.55 - $17.29	467,997	6.91	$ 12.61	296,378	$ 12.01
$17.33 - $17.33	915,430	9.90	$ 17.33		$
$17.37 - $18.50	195,126	8.06	$ 18.13	84,788	$ 17.94
$18.54 - $18.89	632,338	7.94	$ 18.88	316,188	$ 18.89
$18.91 - $23.03	344,372	8.69	$ 20.93	90,696	$ 20.72
$23.31 - $24.60	757,650	8.90	$ 23.34	193,703	$ 23.35
	4,665,037			2,181,977	

At December 31, 2008, the aggregate intrinsic value of the outstanding options was $25.5 million and the aggregate intrinsic value of the exercisable options was $20.6 million. The weighted-average remaining contractual life for exercisable options was 6.68 years.

Note 11. Related Party Transactions

The Company has two agreements with Incyte Corporation, a former stockholder, that were entered into in March 2001: a LifeSeq collaborative agreement and a patent license agreement. Under these agreements, the Company incurred royalties expense of $1.1 million, $627,000 and $270,000 in 2008, 2007 and 2006, respectively.

One of the Company s directors is also a director of Incyte and holds shares, directly or beneficially, of both companies. As of December 31, 2006, to the Company s knowledge, Incyte had divested its holdings in the Company s common stock.

Note 12. Income Taxes

The Company recorded an income tax benefit of $61,000 for the year ended December 31, 2008. The Company recorded minimum state income taxes of $4,000 excluding the impact of a $65,000 discrete item. The discrete item reflects the Company s estimated refundable credit receivable as a result of the enactment of the Housing and Economic Recovery Act of 2008, under which corporations otherwise eligible for bonus first-year depreciation may

instead elect to claim a refund for research and development tax credits generated prior to 2006. No income tax expense or benefit was recorded for the years ended December 31, 2007 or 2006 because the Company has incurred net operating losses since inception.

As of December 31, 2008 and 2007, the Company had deferred tax assets of approximately $64.4 million and $59.6 million, respectively. Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately $4.9 million, $8.9 million and $11.3 million during the years ended December 31, 2008, 2007 and 2006, respectively. Deferred tax assets primarily relate to net operating loss and tax credit carryforwards.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The tax effects of temporary differences and carryforwards that give rise to significant portions of deferred tax assets and liabilities consist of the following:

	December 31,	
	2008	2007
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 52,682	$ 52,508
Research tax credits	4,785	3,396
Capitalized costs	1,216	1,193
Fixed assets	2,163	957
Other	3,599	1,500
Total deferred tax assets	64,445	59,554
Valuation allowance	(64,445)	(59,554)
Net deferred tax assets	$	$

As of December 31, 2008, the Company had federal and state net operating loss carryforwards of approximately $132.2 million and $128.9 million, respectively, and federal and state research and development tax credit carryforwards of approximately $3.1 million and $3.3 million, respectively. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in 2010 if not utilized. The state tax credits have no expiration date.

The Company tracks a portion of its deferred tax assets attributable to stock option benefits in a separate memorandum account pursuant to SFAS 123R. Therefore, these amounts are no longer included in the Company s gross or net deferred tax assets. Pursuant to SFAS 123R, the benefit of these stock options will not be recorded in equity unless it reduces taxes payable. As of December 31, 2008, the portion of the federal and state net operating loss related to stock option benefits was approximately $1.9 million.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations defined by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

The Company adopted FIN 48 as of January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company did not recognize any adjustment to its liability for uncertain tax positions as a result of the implementation of FIN 48, and therefore did not record any adjustment to the beginning balance of retained earnings on its 2007 consolidated balance sheet.

The Company had $575,000 and $413,000 of unrecognized tax benefits as of December 31, 2008 and 2007, respectively. The following table summarizes the activity related to unrecognized tax benefits:

	Year Ended December 31,	
	2008	2007
	(In thousands)	
Balance at January 1	$ 413	$
Increases related to prior year tax positions	9	413
Increases related to current year tax positions	153	
Balance at December 31	$ 575	$ 413

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Interest and penalties related to unrecognized tax benefits would be included as income tax expense in the Company s consolidated statements of operations. As of December 31, 2008, the Company had not recognized any tax-related penalties or interest in its consolidated balance sheets or statements of operations. The Company does not anticipate a material change to its unrecognized tax benefits over the next twelve months. Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business.

The Company files federal and state income tax returns with varying statutes of limitations. Due to the Company s net carryover of unused net operating losses and tax credits, all tax years from 2000 forward remain subject to future examination by tax authorities.

Note 13. Selected Quarterly Financial Data (Unaudited)

The following table contains selected unaudited consolidated statements of operations information for each of the quarters in 2008 and 2007. The Company believes that the following information reflects all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

Quarter Ended	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2008:				
Total revenues	$ 23,440	$ 27,783	$ 28,121	$ 31,235
Product revenues	23,356	26,327	28,070	$ 30,905
Cost of product revenues	5,884	6,850	7,140	7,311
Net loss	(6,634)	(4,099)	(3,022)	(2,334)
Basic and diluted net loss per common share	$ (0.24)	$ (0.15)	$ (0.11)	$ (0.08)
2007:				
Total revenues	$ 14,088	$ 14,690	$ 15,901	$ 19,348
Product revenues	13,146	14,555	15,781	19,264
Cost of product revenues	3,847	4,172	4,398	4,914
Net loss	(6,850)	(7,198)	(7,253)	(5,991)
Basic and diluted net loss per common share	$ (0.28)	$ (0.28)	$ (0.26)	$ (0.21)

The quarterly increases in product revenues and cost of product revenues during 2008 and 2007 were primarily attributable to increased adoption of Onco*type* DX by physicians and increased reimbursement for Onco*type* DX by third-party payors. The increases in revenues and cost of product revenues for the fourth quarter of 2007 and the first quarter of 2008 were also attributable to the inclusion of Onco*type* DX in the American Society of Clinical Oncology s clinical practice guidelines in October 2007 and in the National Comprehensive Cancer Network s clinical practice guidelines in December 2007.

Per share amounts for the quarters and full year have been calculated separately. Accordingly, quarterly amounts may not add to the annual amount because of differences in the weighted-average common shares outstanding during each period, due primarily to the effect of the Company s issuing shares of its common stock during the year.

Basic and diluted net loss per common share are identical as common equivalent shares are excluded from the calculation because their effect is anti-dilutive.

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ITEM 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosures***.

Not applicable.

ITEM 9A. ***Controls and Procedures***.

(a) *Evaluation of disclosure controls and procedures.* We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Management s Annual Report on Internal Control over Financial Reporting.* Our management is responsible for establishing and maintaining internal control over our financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of internal control 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 policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control-Integrated Framework.* Based on the assessment using those criteria, our management concluded that, as of December 31, 2008, our internal control over financial reporting was effective. Our independent registered public accounting firm, Ernst & Young LLP, audited the effectiveness of our internal control over financial reporting. Their report appears below:

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Genomic Health, Inc.

We have audited Genomic Health, Inc. s internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Genomic Health, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

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

In our opinion, Genomic Health, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Genomic Health, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2008 and our report dated March 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 12, 2009

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(c) *Changes in internal controls.* There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 9A(a) above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***Other Information***.

None.

PART III

ITEM 10. ***Directors, Executive Officers and Corporate Governance***.

The information required by this item with respect to directors is incorporated by reference from the information under the caption Election of Directors contained in our Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2009 Annual Meeting of Stockholders to be held on June 8, 2009, or Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption Executive Officers of the Registrant and is incorporated herein by reference.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Conduct that applies to all of our officers and employees, including our Executive Chairman of the Board, our President and Chief Executive Officer, our Chief Operating Officer and Chief Financial Officer and other employees who perform financial or accounting functions. The Code of Business Conduct sets forth the basic principles that guide the business conduct of our employees. We have also adopted a Senior Financial Officers Code of Ethics that specifically applies to our Executive Chairman of the Board, our President and Chief Executive Officer, our Chief Operating Officer and Chief Financial Officer, and key management employees. Stockholders may request a free copy of our Code of Business Conduct and Ethics and our Senior Financial Officers Code of Ethics by contacting Genomic Health, Inc., Attention: CFO, 301 Penobscot Drive, Redwood City, California 94063.

To date, there have been no waivers under our Code of Business Conduct and Ethics or Senior Financial Officers Code of Ethics. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or Senior Financial Officers Code of Ethics or any waivers, if and when granted, of our Code of Business Conduct and Ethics or Senior Financial Officers Code of Ethics on our website at *http://www.genomichealth.com* within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee, comprised of Mr. Randall S. Livingston, as Chairman, Mr. Samuel D. Colella and Dr. Fred E. Cohen. The Board of Directors has determined that Mr. Livingston qualifies as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an independent director under the current rules of The NASDAQ Stock Market and Securities and Exchange Commission rules and regulations.

ITEM 11. ***Executive Compensation***.

The information required by this item is incorporated by reference from the information under the captions Election of Directors Compensation of Directors and Executive Compensation contained in the Proxy Statement.

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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 under the captions Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information contained in the Proxy Statement.

ITEM 13. ***Certain Relationships and Related Transactions, and Director Independence.***

The information required by this item is incorporated by reference from the information under the caption Certain Relationships and Related Transactions contained in the Proxy Statement.

ITEM 14. ***Principal Accounting Fees and Services***.

The information required by this item is incorporated by reference from the information under the caption Principal Accountant Fees and Services contained in the Proxy Statement.

PART IV

ITEM 15. ***Exhibits and Financial Statement Schedules.***

(a) *Documents filed as part of this report:*

(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Genomic Health under Item 8 of Part II hereof.

(2) Financial Statement Schedules

The following schedule is filed as part of this Form 10-K:

Schedule II Valuation and Qualifying Accounts for the years ended December 31, 2008, 2007, and 2006.

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

(3) Exhibits

See Item 15(b) below. Each management contract or compensatory plan or arrangement required to be filed has been identified.

(b) *Exhibits*

Exhibit No.	Description of Document
3(i)	Restated Certificate of Incorporation of the Company (incorporated by reference to exhibit 3.3 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on

September 28, 2005).

3(ii) Amended and Restated Bylaws of the Company, as amended and restated January 8, 2009 (incorporated by reference to exhibit 3.1 to the Company s Current Report on Form 8-K filed on January 9, 2009).

4.1 Specimen Common Stock Certificate (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).

4.2 Amended and Restated Investors Rights Agreement, dated February 9, 2004 between the Company and certain of its stockholders (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).

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Exhibit No.	Description of Document
10.1#	Form of Indemnification Agreement between the Company and its officers and directors (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.2#	2001 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.3#	2005 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.1	Sublease Agreement dated June 1, 2001 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.2	First Amendment to Sublease Agreement dated October 29, 2003 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.3	Second Amendment to Sublease Agreement dated January 31, 2005 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.5	PCR Patent License Agreement dated February 21, 2005 between the Company and Roche Molecular Systems, Inc. (incorporated by reference to exhibit 10.8 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.6.1	Master Security Agreement dated March 30, 2005 between the Company and Oxford Finance Corporation (incorporated by reference to exhibit 10.9.1 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.6.2	Form of Promissory Note (Equipment) issued by the Company in favor of Oxford Finance Corporation (incorporated by reference to exhibit 10.9.2 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.6.3	Form of Promissory Note (Computers and Software) issued by the Company in favor of Oxford Finance Corporation (incorporated by reference to exhibit 10.9.3 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.6.4	Schedule of Promissory Notes issued by the Company in favor of Oxford Finance Corporation (incorporated by reference to exhibit 10.6.4 filed with the Company s Annual Report on Form 10-K for the year ended December 31, 2006).
10.7	Lease dated September 23, 2005 between the Company and Metropolitan Life Insurance Company (incorporated by reference to exhibit 10.10 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.8	Lease dated January 2, 2007 between the Company and Metropolitan Life Insurance Company (incorporated by reference to exhibit 10.8 filed with the Company s Annual Report on Form 10-K for the year ended December 31, 2006).
10.9#	Form of Non U.S. Employee/Consultant Stock Option Agreement under the Company s 2005 Stock Incentive Plan (incorporated by reference to exhibit 10.1 filed with the Company s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2008).
12.1*	Statement Regarding Computation of Ratios.
21.1	List of Subsidiaries (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).

23.1*	Consent of independent registered public accounting firm.
24.1*	Power of Attorney (see page 86 of this Form 10-K).
31.1*	Rule 13a 14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a 14(a) Certification of the Chief Financial Officer.

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Exhibit No.	Description of Document
32.1**	Statement of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
32.2**	Statement of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).

* Filed herewith.

** In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management s Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed filed for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Confidential treatment has been granted with respect to certain portions of these agreements.

# Indicates management contract or compensatory plan or arrangement.

Copies of above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Genomic Health, Inc., 301 Penobscot Drive, Redwood City, California 94063.

(c) *Financial Statements and Schedules*

Reference is made to Item 15(a)(2) above.

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SCHEDULE II

GENOMIC HEALTH, INC.
VALUATION AND QUALIFYING ACCOUNTS
Years Ended December 31, 2008, 2007 and 2006

	Balance at Beginning of Period	Additions Charged (Credited) to Expenses	Deductions	Balance at End of Period
		(In thousands)		
Allowance for Doubtful Accounts:				
Year ended December 31, 2008	$ 133	$ 1,343	$ 595	$ 881
Year ended December 31, 2007	$ 510	$ (115)[1]	$ 262	$ 133
Year ended December 31, 2006	$	$ 562	$ 52	$ 510

(1) Changes in the Company s estimate of allowance for doubtful accounts resulted in the reduction of bad debt expense for the year ended December 31, 2007.

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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.

GENOMIC HEALTH, INC.

By: /s/ Kimberly J. Popovits
Kimberly J. Popovits
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 13, 2009

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Randal W. Scott, Kimberly J. Popovits and G. Bradley Cole, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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.

Signature	Title	Date
/s/ Kimberly J. Popovits Kimberly J. Popovits	President and Chief Executive Officer Director (Principal Executive Officer)	March 13, 2009
/s/ G. Bradley Cole G. Bradley Cole	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 13, 2009
/s/ Randal W. Scott Randal W. Scott, Ph.D.	Executive Chairman of the Board of Directors	March 13, 2009
/s/ Julian C. Baker Julian C. Baker	Director	March 13, 2009
/s/ Brook H. Byers	Director	March 13, 2009

Brook H. Byers		
/s/ Fred E. Cohen	Director	March 13, 2009
Fred E. Cohen, MD., D. Phil.		
/s/ Samuel D. Colella	Director	March 13, 2009
Samuel D. Colella		

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Signature	Title	Date
/s/ Ginger L. Graham Ginger L. Graham	Director	March 13, 2009
/s/ Randall S. Livingston Randall S. Livingston	Director	March 13, 2009
/s/ Woodrow A. Myers Woodrow A. Myers Jr., MD	Director	March 13, 2009

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EXHIBIT INDEX

Exhibit No.	Description of Document
3(i)	Restated Certificate of Incorporation of the Company (incorporated by reference to exhibit 3.3 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
3(ii)	Amended and Restated Bylaws of the Company, as amended and restated January 8, 2009 (incorporated by reference to exhibit 3.1 to the Company s Current Report on Form 8-K filed on January 9, 2009).
4.1	Specimen Common Stock Certificate (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
4.2	Amended and Restated Investors Rights Agreement, dated February 9, 2004 between the Company and certain of its stockholders (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.1#	Form of Indemnification Agreement between the Company and its officers and directors (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.2#	2001 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.3#	2005 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.1	Sublease Agreement dated June 1, 2001 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.2	First Amendment to Sublease Agreement dated October 29, 2003 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
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