GENOMIC HEALTH INC
Form 10-K
March 11, 2011

Table of Contents

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, 2010

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	**94063**
(Address of principal executive offices)	*(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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o 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, 2010, the aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant was approximately $206.8 million, based on the closing price of the common stock as reported on the NASDAQ Global Market for that date.

There were 29,116,257 shares of the registrant s Common Stock issued and outstanding on February 28, 2011.

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 2011 Annual Meeting of Stockholders to be held on June 9, 2011.

TABLE OF CONTENTS

Table of Contents

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 similar 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, a significant amount of our revenues will be derived from Oncotype DX for breast cancer; the factors that may impact our financial results; the extent of our net losses and our ability to achieve sustained profitability; our ability to recognize revenues other than on a cash basis; our business strategy and our ability to achieve our strategic goals; our expectations regarding product revenues; 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 reimbursement from third-party payors and government insurance programs for new tests or in new markets; our expectations regarding our international expansion and opportunities, and our expectations regarding revenues from international sales; our intent to enter into additional foreign distribution arrangements; the factors we believe to be driving demand for our tests 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 and our sales forces capacity to sell our tests; plans for, and the timeframe for the development or commercial launch of, future tests or enhancements to address different patient populations of breast or colon cancer, other types of cancer or specific cancer treatments; 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; the occurrence, timing, outcome or success of clinical trials or studies; our plans with respect to additional development or clinical studies; our expectations regarding timing of the announcement or publication of research results; the benefits of our technology platform; the economic benefits of our tests to the healthcare system; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive benefits; our expectations regarding the ability of our technology to continue to increase throughput; our expectations regarding our future technologies and their potential benefits; our belief that multi-gene analysis provides better analytical information; our beliefs regarding the benefits of genomic analysis in various patient populations; our expectations regarding clinical development processes future tests may follow; our beliefs regarding the benefits of individual gene reporting; our expectation that our research and development, general and administrative and sales and marketing expenses will increase and our anticipated uses of those funds; our expectations regarding capital expenditures; 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 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 expectations regarding incurrence of debt; our compliance with federal, state and foreign regulatory requirements; the potential impact resulting from the regulation of our tests by the U.S. Food and Drug Administration, or FDA, and our belief that our tests are 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 or our valuation allowance; 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; and anticipated trends and challenges in our business and the markets in which we operate.

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 or maintain reimbursement for our existing tests or any future tests we may develop; the risk that reimbursement pricing may change; the risks and

Table of Contents

uncertainties associated with the regulation of our tests by the FDA; the impact of new legislation or regulations on our business; 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 attributable to both the Mattson Jackson Group, Inc. s CancerMpact database (November 2010) and the Summary of Globocan 2008 Data published by the International Journal of Cancer in June 2010, or data that we derived from these sources. These sources generally indicate that they believe their information is reliable but do not guarantee the accuracy and completeness of their information. Although we believe that the sources 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 molecular diagnostics company focused on the development and global commercialization of genomic-based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. Our Onco*type* DX platform utilizes quantitative genomic analysis in standard tumor pathology specimens to provide tumor-specific information, or the oncotype of a tumor. In January 2004, we launched our first test for early stage breast cancer patients. Our Onco*type* DX breast cancer test has extensive clinical evidence validating its ability to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit. We offer the Onco*type* DX breast cancer test as a clinical service, where we analyze the expression levels of 21 genes in tumor tissue samples and provide physicians with a quantitative gene expression profile expressed as a single quantitative score, which we call a Recurrence Score. The test also provides 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.

The Onco*type* DX breast cancer test has been extensively evaluated in thirteen independent studies involving more than 4,000 breast cancer patients, including a large validation study published in *The New England Journal of Medicine* in December 2004 and a chemotherapy benefit study published in the *Journal of Clinical Oncology* in May 2006. The American Society of Clinical Oncologists, or ASCO, and the National Comprehensive Cancer Network, or NCCN, clinical practice guidelines include the use of our Onco*type* DX breast cancer test to predict the likelihood of disease recurrence and the likelihood of chemotherapy benefit for a large portion of early stage breast cancer patients. As of December 31, 2010, we had received breast cancer test samples from more than 60 countries and established exclusive distribution agreements for our Onco*type* DX breast cancer test with distributors in 13 countries outside of the United States.

In January 2010, we launched our second product, the Onco*type* DX colon cancer test, the first multigene expression test developed to assess the risk of recurrence in patients with stage II disease. We offer the Onco*type* DX colon cancer test as a clinical service, where we analyze the expression levels of 12 genes in tumor tissue samples and provide physicians with a Recurrence Score result. For our Onco*type* DX colon cancer test, we used the same rigorous clinical development strategy and standardized quantitative technology designed for our Onco*type* DX breast cancer

test. We 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 conducted an independent clinical validation study in stage II colon cancer for our test, utilizing more than 1,400 patient samples, which demonstrated that the Onco*type* DX colon cancer test can independently predict individual recurrence risk in stage II colon cancer patients following surgery. Based on our experience in obtaining adoption of and reimbursement for our Onco*type* DX breast cancer test, we do

Table of Contents

not expect product revenues from our colon cancer test to comprise more than 10% of our total revenues for at least the next year or more.

The Onco*type* DX breast and colon cancer tests are commercially available at list prices of $4,075 and $3,200, respectively, 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. As of December 31, 2010, more than 190,000 Onco*type* DX tests had been delivered for use in treatment planning. Our headquarters is located in Redwood City, California, and we have a European subsidiary located in Geneva, Switzerland.

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 2010, approximately 1.6 million people in the United States and 12.7 million people worldwide were 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. Cancer treatment decisions may include whether or not to perform surgery, whether or not to administer chemotherapy, and whether or not to utilize other targeted therapies.

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 grade and staging are heavily dependent on visual assessment and human interpretation, physicians and patients often make treatment decisions 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.

Table of Contents

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 ribonucleic acid, or 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.

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 genomic analysis, including gene expression, 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 the likelihood of recurrence or response to therapy 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.

Oncotype DX Platform

Our Onco*type* DX platform uses our quantitative molecular pathology approach to improve cancer treatment decisions. Our diagnostic approach correlates gene expression to clinical outcomes and provides an individualized analysis of each patient s tumor. We have built a diagnostic infrastructure that allows us to move from research into development through to processing actual patient samples in our clinical reference laboratory. 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 the likelihood of cancer recurrence or progression or responsiveness to therapy. 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. This information ultimately allows the physician and patient to choose a course of treatment that is individualized for each patient.

Our service fits within current clinical practice and therapeutic protocols, facilitating product adoption. We offer Onco*type* DX as a clinical laboratory test, where we analyze tumor tissue samples in our clinical reference

Table of Contents

laboratory and provide physicians with genomic information specific to the patient s tumor. We analyze tissues as they are currently handled, processed and stored by clinical pathology laboratories. Once a patient is diagnosed and the treating physician places an order for an Onco*type* DX test, the local pathology laboratory 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. We believe this provides an advantage over tests using fresh or frozen tissue that generally require special handling, such as shipping frozen tissue on dry ice.

Once we receive the tumor sample, it is logged in and processed by our pathology department. Anatomic pathologists perform quality control by reviewing each sample that comes into our clinical reference laboratory, ensuring that the indicated cancer is present and that the specimen is suitable for further processing. Suitable samples then undergo a process by which RNA is extracted and purified. We then analyze the resulting material and produce a report that shows a single quantitative score, which we call a Recurrence Score, on a continuum between 0-100. The Recurrence Score report is delivered to the treating physician within 10 to 14 days of our 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. The continuous range of scores differentiates Onco*type* DX tests from other tests that predict only high or low risk by providing an individualized level of risk. 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. The Recurrence Score result, along with other data and tests that physicians obtain, forms the basis for the treatment decision.

We believe our service 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 that 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 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. For example, 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 the Onco*type* DX breast cancer test s list price of $4,075. On the other hand, some high risk breast cancer 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 Breast Cancer Test

In 2010, approximately 280,000 people in the United States and 1.4 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,

nodal 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, which includes DCIS, generally refers to a pre-invasive tumor with reduced risk of recurrence. DCIS is typically not treated with chemotherapy but may be

Table of Contents

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. Prior to the inclusion of our Onco*type* DX breast cancer test in clinical guidelines, standard treatment guidelines weighed 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

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 were classified as high risk under these guidelines. As a consequence, the use of chemotherapy became 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 was a difficult decision under previous guidelines. A National Surgical Adjuvant Breast and Bowel Project, or NSABP, study published by *The New England Journal of Medicine* in December 2004 demonstrated that the incremental survival benefit of chemotherapy in N-, ER+ patients also treated with tamoxifen is 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.

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 breast cancer Recurrence Score. Our clinical validation study with the NSABP Study B-14 population, published by *The New England Journal of Medicine* in December 2004, demonstrated that the breast cancer Recurrence Score correlated with an individual s likelihood of distant recurrence within 10 years of diagnosis. Moreover, our study with the NSABP B-20 population, published in the *Journal of Oncology* in May 2006, demonstrated that the breast cancer Recurrence Score also correlates with the likelihood of chemotherapy benefit.

Clinical Utility and Health Economic Benefit

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 our Onco*type* DX breast cancer test. Three of the studies assessing the impact of our test on treatment decisions concluded that use of the test resulted in fewer recommendations for and less use of chemotherapy, demonstrating the actionable nature of our Onco*type* DX breast cancer test in its ability to help reduce unnecessary use of chemotherapy. In September 2008, the *Journal of Clinical Oncology* published clinical results suggesting that the Onco*type* DX breast cancer 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 of N-, ER+ patients indicating that our test significantly changed treatment recommendations versus standard measures alone.

In January 2010, the *Journal of Clinical Oncology* published a study showing knowledge of a patient s breast cancer Recurrence Score result changed approximately 30% of treatment decisions, and a separate study demonstrating that our test significantly predicts local or regional breast cancer recurrence. In December 2010, we presented three studies at the SABCS supporting the clinical utility of our breast cancer test for N-, ER+ patients,

including a meta-analysis of seven studies demonstrating a consistent and large impact of the Recurrence Score result on breast cancer adjuvant treatment decisions, an analysis showing that the Recurrence Score result used alone remains the recommended method to predict relative chemotherapy benefit in N-, ER+ disease, and a study demonstrating that patient age alone does not capture differences in underlying individual tumor biology as the Recurrence Score result does.

Single Gene Reporting (ER, PR, HER2)

We began providing quantitative gene expression reporting for ER and PR genes with the Onco*type* DX breast cancer test 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 our Onco*type* DX breast cancer test 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 our breast cancer test in assessing HER2 status.

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

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 our Onco*type* DX breast cancer test 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, or ECOG, 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 the Recurrence Score result provides 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, or SWOG, suggesting that our test may be useful in predicting survival without disease recurrence and chemotherapy benefit for N+ patients, in addition to N-, ER+ patients.

At SABCS in December 2009, we presented two studies reinforcing the clinical utility of our Onco*type* DX breast cancer test for N+ patients. One study, completed in collaboration with SWOG and published in *Lancet Oncology* in January 2010, reinforced the conclusion that chemotherapy does not appear to benefit patients with either 1-3 or 4 or more positive nodes for disease-free survival over 10 years, if their tumors had a low Recurrence Score result. A separate abstract presented at SABCS in December 2009 demonstrated that physicians who use our Onco*type* DX breast cancer test for N+ patients frequently change their treatment decisions based on Recurrence Score results, with an overall reduction in chemotherapy treatment recommendations.

Aromatase Inhibitors

We conducted studies of our Onco*type* DX breast cancer test 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 March 2010, the *Journal of Clinical Oncology* published results from a European study using our test to analyze tumor samples from over 1,200 patients in the ATAC (Arimedix, Tamoxifen, Alone or in Combination) trial, which established the wide use of aromatase inhibitors for adjuvant treatment of postmenopausal women with hormone receptor-positive breast cancer. The study demonstrated that, along with other standard measures such as tumor size, our Onco*type* DX breast cancer test

contributes independently to provide a more complete picture of prognosis for N- and N+ patients treated with aromatase inhibitors.

Table of Contents

ER Assessment

In September 2009, we began accepting all appropriate breast cancer tumor samples, regardless of immunohistochemistry, or IHC, ER status, to facilitate assessment of uncertain ER status by either IHC or RT-PCR testing. An Onco*type* DX breast cancer Recurrence Score result is generated if the ER status is positive by IHC or positive by RT-PCR, even if the sample was negative by IHC when submitted, allowing more patients to benefit from the information provided by our test.

Health Economic Benefits

We sponsor third-party studies conducted by researchers affiliated with academic institutions to examine the health economic implications of our Onco*type* DX breast cancer test. Two such studies, one of which was published in *The American Journal of Managed Care* in May 2005, demonstrated that our test provided a more accurate classification of risk than the NCCN guidelines in place at that time 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 our Onco*type* DX breast cancer test 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 result to identify which patients would benefit from chemotherapy should lead to larger reductions in projected overall costs. According to this model, if all early stage breast cancer patients and their physicians used our test and acted on the information provided by the breast cancer Recurrence Score result, there would be significant economic benefit to the healthcare system.

International Studies

We have completed or initiated multiple international clinical studies intended to support the adoption of our Onco*type* DX breast cancer test outside of the United States. During the second quarter of 2009, we initiated our first Taiwanese Chinese population study in collaboration with the National Taiwan University. In September 2009, we announced results of a study confirming that the distribution of Recurrence Score results in European and Middle Eastern breast cancer patients is consistent with those observed in patients in the United States. In November 2010, *Breast Cancer Research Treatment* published positive results from a Japanese economic evaluation study demonstrating that the inclusion of our Onco*type* DX breast cancer test in Japan s social health insurance benefit package would be cost effective. In December 2010, we presented positive preliminary results from a large adjuvant breast cancer trial with clinical researchers in Germany using our test to select patients for study randomization and treatment. We are also conducting or have initiated clinical utility trials of our breast cancer test with clinical researchers in Australia, Canada, Japan, Mexico, Spain and the United Kingdom.

Oncotype DX Colon Cancer Test

In 2010, approximately 105,000 people in the United States and 870,000 people worldwide were diagnosed with colon cancer. Following diagnosis, a physician determines the stage of the colon cancer by examining the following:

- the pathology of the tumor,
- the size of the tumor,

nodal 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.

Colon cancer tumors are classified as stage 0, I, II, III or IV. Stage 0 generally refers to a pre-invasive tumor with reduced risk of recurrence that is typically not treated with chemotherapy but may be treated with surgery.

Table of Contents

Standard treatment guidelines weigh the stage of the cancer and additional factors to predict cancer recurrence and determine treatment protocol including:

- the age of the patient,
- the histological type and grading of the tumor as reported by the pathologist,
- the level of mismatch repair, or MMR, also known as microsatellite instability, or MSI, and
- T-stage, an index of tumor penetration through the bowel.

In 2010, stage II colon cancer affected approximately 30,000 people in the United States, and the current treatment paradigm is unclear. The decision to treat patients with chemotherapy following surgery is based on an assessment of how likely their disease is to recur. However, accurately identifying those patients with high recurrence risk is a critical issue for physicians because the available markers to determine likelihood of disease recurrence are limited, resulting in both over-treatment and under-treatment of patients following surgery. 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 was no clinically validated genomic test available that predicted the likelihood of recurrence for individual patients prior to the availability of our test.

In developing our colon cancer product, we used the same rigorous clinical development strategy and standardized quantitative technology designed for our Onco*type* DX breast cancer test. We developed our gene panel by identifying 761 cancer-related genes through review of existing research literature and computer analysis of genomic databases. The NSABP conducted three development studies and the Cleveland Clinic Foundation conducted one development study, which we funded, analyzing the 761 candidate genes in over 1,800 patients with stage II colon cancer. Detailed analysis of gene expression and colon cancer recurrence was performed to identify specific genes with the potential to predict the likelihood of cancer recurrence and response to chemotherapy. The 761 candidate genes were also examined to determine whether they would be useful beyond other key variables including tumor stage, tumor grade, lymph nodes examined and MMR/MSI.

We selected a final set of 12 genes which were then independently evaluated in a validation study of over 1,400 stage II colon cancer patients from the Quick and Simple and Reliable, or QUASAR, randomized study of adjuvant chemotherapy in the United Kingdom. This international, multi-center randomized trial examined the recurrence risk and the benefit associated with 5-fluorouracil/leucovorin, or 5FU/LV, adjuvant chemotherapy. Gene expression was quantified by RT-PCR from manually microdissected FPE primary colon cancer tissue, and recurrence-free interval, disease-free survival and overall survival were analyzed.

In May 2009, we announced positive results from this clinical validation study. The study met its primary endpoint to predict the likelihood of recurrence for stage II colon cancer patients following surgery and showed that the colon cancer Recurrence Score provided additional independent clinical value beyond standard measures of risk. The study showed that the colon cancer Recurrence Score result maintained significance, independent of MMR/MSI, T-stage, nodes examined, grade and lymphovascular invasion. We believe this addresses an unmet need in the treatment of colon cancer by validating a clinical tool that can significantly improve risk assessment in the treatment planning for stage II colon cancer patients. T4 stage and MMR deficiency were also independently beneficial in predicting recurrence, and together comprise approximately 25 percent of patients. T4 stage indicates growth of the tumor through the wall of the bowel and is associated with higher risk of recurrence. MMR/MSI is an alteration observed in approximately 15 percent of colon cancers. Patients with tumors identified as MSI high, or MMR deficient, are considered to be at low risk of recurrence. We expect that the publication of the results from this study, planned for

2011, will help to support adoption of and reimbursement for our Onco*type* DX colon cancer test. Based upon our experience in obtaining adoption and reimbursement for our breast cancer test, we do not expect product revenues from our colon cancer test to comprise more than 10% of our total revenues for at least the next year or more.

Table of Contents

Clinical Utility

We believe the Onco*type* DX colon cancer Recurrence Score result will provide the greatest clinical utility for treatment selection in the more than 70 percent of patients for whom MMR/MSI and T-stage are uninformative. At the January 2010 ASCO Gastrointestinal Cancers Symposium, we presented results from a study demonstrating that the Onco*type* DX colon cancer Recurrence Score result and number of nodes examined are independent predictors of recurrence in stage II colon cancer and both should be considered when assessing individual recurrence risk in this patient population. We are conducting a second stage II colon cancer recurrence study and plan to report results in the first half of 2011. In June 2010, we initiated the first treatment decision impact study of our colon cancer test and are enrolling patients. We are planning additional studies to support the clinical utility and assess the treatment impact and health economic benefit of our Onco*type* DX colon cancer test.

Product Development

We developed our Onco*type* DX tests 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 3,000 individual gene assays. 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. In addition, through our investigator sponsored trial program, we provide physicians with our tests for use in specific patient populations to be used in treatment decisions.

Product Development Opportunities

Ductal Carcinoma in Situ (DCIS)

In 2010, approximately 60,000 patients in the United States and 280,000 patients worldwide were diagnosed with stage 0 breast cancer, including DCIS. We are investigating the utility of Onco*type* DX in patients with DCIS. In early

2010, we presented positive results from a DCIS breast cancer feasibility study demonstrating that RNA extraction and RT-PCR technology can be successfully performed to assess gene expression profiles from FPE tissues. We plan to evaluate the use of the Onco*type* DX 21-gene breast cancer panel and also seek to identify other genes that may be used for treatment planning in DCIS. We are currently conducting a DCIS clinical validation study and plan to report results in 2011. Depending upon the results of these studies, we expect to launch a DCIS test that predicts likelihood of recurrence in late 2011 if the test uses the existing Onco*type* DX 21-gene breast cancer panel, or in 2013 if the test uses other existing or new genes and gene combinations.

Table of Contents

Other Breast Cancer Populations

We continue to conduct research and development studies in other breast cancer populations. At the May 2009 ASCO meeting, we presented results from a clinical study that summarized the gene signatures of male patients for whom the Onco*type* DX breast cancer test was used to guide chemotherapy treatment, indicating that breast cancer in men displays similar gene signatures to female breast cancer. We also presented a separate study at the ASCO meeting demonstrating that there were significant differences in gene expression between hormone receptor negative, or triple negative, breast cancer compared with hormone receptor positive disease.

MMR/MSI Status

The QUASAR clinical validation study demonstrated that MMR/MSI status, an alteration observed in approximately 15 percent of colon cancers, was independently beneficial in predicting colon cancer recurrence. MMR/MSI testing, although not routinely performed, is currently provided by many pathology laboratories. In order to advance the incorporation of MMR/MSI testing in colon cancer treatment decisions, we are planning to provide MMR test results in 2011.

Stage III Colon Cancer Recurrence

We are investigating the utility of the Onco*type* DX colon cancer test in stage III colon cancer, which affects over 25,000 patients each year in the United States. At the January 2010 ASCO Gastrointestinal Cancers Symposium, we presented study results from an analysis of various biological similarities and differences between stage II and stage III colon cancer suggesting the Onco*type* DX colon cancer Recurrence Score result is stage independent, and that it may also predict recurrence risk in stage III colon cancer. In June 2010, we presented positive results from an evaluation of biological similarities and differences between stage II and stage III colon cancer suggesting the Onco*type* DX colon cancer Recurrence Score result may also predict recurrence risk in stage III colon cancer. We plan to continue conducting early development studies to evaluate our Onco*type* DX colon cancer test for treatment planning in stage III disease. Depending upon the results of these studies, we expect to launch a test that predicts likelihood of recurrence in stage III colon cancer in 2013.

Stage II and III Colon Cancer Chemotherapy Benefit

We are conducting both early development and development studies to investigate the Onco*type* DX colon cancer test s ability to predict chemotherapy benefit in stage II and stage III colon cancer patients treated with oxaliplatin. Depending upon the outcome of these studies, we expect to launch a test that predicts the benefit of oxaliplatin chemotherapy for stage II and stage III colon cancer patients in 2013.

Prostate Cancer

Approximately 900,000 men worldwide were diagnosed with prostate cancer in 2010. Based upon the results of prostate-specific antigen, or PSA, testing, biopsies were performed on over 750,000 men in the United States in 2010, and approximately 250,000 of these patients were diagnosed with prostate cancer. The vast majority of these patients receive aggressive treatment, including surgery and radiation therapy, and more than half of these patients suffer incontinence and/or impotence after surgery. Less than 10% of patients choose active surveillance even though, for most of these patients, their disease will never cause clinical symptoms or death. In December 2010, we presented positive first results from our prostate gene identification study. The study, which applied the same RT-PCR technology used in our Onco*type* DX breast and colon cancer tests, identified 295 genes strongly associated with clinical recurrence of prostate cancer following radical prostatectomy. Based on these results, we announced that we are moving forward with full clinical development and plan to conduct multiple additional studies. We expect to

report full gene identification results in 2011 and finalize analytical methods to support a clinical validation study in 2012. Depending on the results of these studies, we expect to launch a test in 2014 which, in conjunction with the Gleason score, or tumor grading, we believe may improve treatment decisions for prostate cancer patients.

Table of Contents

Renal Cancer

In 2010, approximately 48,000 people in the United States and 275,000 people worldwide were diagnosed with renal cancer. In June 2010, we presented results from our first renal gene identification study under our collaboration agreement with Pfizer Inc. 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. The study demonstrated a strong correlation between gene expression and recurrence risk in this patient population. Based on these results, we plan to move forward with a clinical validation study and to continue to evaluate a potential renal cancer product depending upon results of validation studies for specific therapies.

Other Cancers

We continue to review and evaluate programs in other cancers. In 2010, approximately 170,000 people in the United States and 1.4 million people worldwide were diagnosed with non-small cell lung cancer. We have conducted early development studies for a test to predict risk of recurrence for early stage non-small cell lung cancer patients. In 2010, approximately 75,000 people in the United States and 200,000 people worldwide were diagnosed with melanoma. We have conducted initial feasibility studies for the development of a test to predict risk of recurrence in melanoma patients.

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 us commercial rights to diagnostic tests that may result from the collaboration. In February 2011, the *British Journal of Cancer* published results from early studies with Bristol-Myers Squibb and ImClone, which identified a small number of genes that could predict response to Erbitux. We may undertake further studies for the development of an EGFR inhibitor response test.

Targeted therapies in breast cancer

We entered into collaborative agreements with Aventis and ECOG 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 stage breast cancer and 0-3 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 breast cancer Recurrence Score result 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 taxane treatment with a possible product launch in 2014.

Table of Contents

Technology

We utilize existing technologies, such as RT-PCR, and information technologies and optimize and integrate them into new processes. We are also incorporating new technologies, such as high-throughput next generation sequencing, or NGS, in our research and development laboratory. 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 process 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 and are developing new and improved technologies for optimized and automated methods for extraction and analysis of RNA from FPE tissue.

Amplify and Detect Diminished Amounts of RNA Consistently

We currently use RT-PCR as the basis for our quantitative molecular pathology assays performed in our clinical reference laboratory. 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.

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 Thousands of Genes from Small Amounts of Tissue

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. We now 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.

We are investigating technologies for assaying low liquid volumes and amplifying trace amounts of RNA in order to develop products that can evaluate smaller amounts of available tissue, including prostate biopsies and

Table of Contents

DCIS. We are also developing NGS to be our primary technology for future gene discovery. NGS technologies parallelize the sequencing process, producing thousands or millions of sequences at once. These technologies are intended to provide nucleic acid sequence information at lower cost than standard methods. We have created proprietary methods for NGS of FPE tissue nucleic acids, created bioinformatics programs and infrastructure for data storage and analysis, and plan to rely on NGS as the basic source of new biomarker discovery in the future. We expect to select NGS as our platform for process development in 2012 and begin using NGS for clinical development in 2013.

Employ Advanced Information Technology

We have developed computer programs to automate our RT-PCR and NGS assay processes. 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. We are investigating methods to further automate our workflow by automating the RNA extraction process.

Commercial Operations

United States

Our commercial infrastructure, including our sales force, managed care group, and patient support network, is critical to our future success. We are continuing 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 with regional and local experience is necessary in order to effectively serve the oncology community. We believe our direct sales approach, targeting oncologists and cancer surgeons, and our medical education and scientific liaisons, targeting key opinion leaders, 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 third-party payors. Due to significant overlap between breast and colon oncologists and surgeons, we believe our current sales force has sufficient capacity to market both our Onco*type* DX breast and colon cancer tests.

We have a managed care department that works with our contract and reimbursement teams to ensure our tests are being used effectively. Our call center and patient support network handle benefits investigation, preauthorization, and precertification for patients who use our tests. We have the infrastructure, if needed, to appeal every claim for our tests that is denied by a third-party payor in order to support the use and encourage adoption of our tests. In addition, we provide patient education through our website, material provided to local advocacy groups, local and national media campaigns and materials provided to oncologists and surgeons.

All Onco*type* DX tests are processed in our clinical reference laboratory facility in Redwood City, California. Our current clinical reference laboratory processing capacity is 18,000 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. As test processing for our Onco*type* DX breast and colon cancer tests is essentially the same, except that the tests utilize different RNA extraction methods and analyze different genes, we believe that we currently have sufficient capacity to process both of our tests.

International

We believe our future success is also dependent on our ability to continue to expand our international commercial presence. We plan to continue to use essentially the same business model internationally as we use in the United States, however, there are significant differences between countries that need to be considered. For example, different countries may have a public healthcare system, a combination of public and private healthcare system or a cash-based payment system. Our initial commercialization efforts in markets outside the of the United States have focused on offering products on a patient self-pay basis and, over time, seeking coverage from public health systems and private insurance on a country by country basis. We have sales representatives in certain

Table of Contents

countries outside of the United States. We may decide to work directly on our own in certain countries while continuing to utilize distributors in other countries. We established a European subsidiary in February 2009 and have lead executives with assignments in the Americas, Europe and Asia to support our international efforts.

We expect that international sales of our Onco*type* DX tests will be heavily dependent on the availability of reimbursement. 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. We expect that it will take several years to establish broad coverage and reimbursement for our tests in countries outside of the United States.

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 in the United States, patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, bill third-party payors for testing. Reimbursement of our Onco*type* DX tests by third-party payors is essential to our commercial success.

Where there is a payor policy, contract or agreement in place, we bill the third payor, the hospital or referring laboratory as well as the patient (for deductibles and coinsurance or copayments, where applicable) in accordance with established policy terms. Where there is no payor policy in place, we pursue reimbursement on behalf of each patient on a case-by-case basis. Our efforts on behalf of these 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.

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 third party 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 an Onco*type* DX test, and the local Medicare carrier for California with jurisdiction to process claims submitted by us decides whether or not and at what rate Medicare will cover the test when billed by us. 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 our Onco*type* DX tests.

Oncotype DX Breast Cancer Test

We have focused substantial resources on obtaining reimbursement coverage for our Onco*type* DX breast cancer test. We believe the key factors driving adoption of our Onco*type* DX breast cancer test include our ongoing commercial efforts, continued publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use and reimbursement of our Onco*type* DX breast cancer test, clinical presentations at major symposia, and the inclusion of our Onco*type* DX breast cancer test in clinical practice guidelines.

Most national and regional third-party payors in the United States, along with the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, have issued positive coverage determinations for our Onco*type* DX breast cancer test for patients with node negative, or N-, estrogen receptor positive, or ER+, disease through contracts, agreements or policy decisions. In June 2009, the local carrier with jurisdiction for claims submitted by us for Medicare patients extended its coverage for our breast cancer test to include ER+ patients with node positive, or N+, disease (up to three positive lymph nodes). Additionally, some payors provide policy coverage for the use of our test in ER+ patients with N+ disease, including lymph node micro-metastasis (greater than 0.2 mm, but not greater than 2.0 mm in size). However, we may not be able to obtain reimbursement coverage from other

payors for our test for breast cancer patients with N+, ER+ disease.

Under current Medicare billing rules, claims for Onco*type* DX breast cancer 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

Table of Contents

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 to purchase these tests, 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 1% of our total breast cancer 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. Under recently enacted healthcare reform legislation, Congress authorized a two year, $100 million demonstration project under which certain tests subject to the 14 day billing rule may be billed directly by the laboratory performing the test rather than the hospital storing the specimen. At this time, we do not know whether our tests will be eligible for this demonstration project or, if eligible, whether the conditions will be favorable for us to participate. We have no assurance that Medicare will revise or reverse these billing rules to allow us to bill for these tests, or that Congress will require Medicare to do so at some point in the future, and we also cannot ensure that hospitals will agree to arrangements to pay us for tests performed on patients falling under these rules.

In January 2008, Medi-Cal became the first Medicaid payor to establish a policy covering our Onco*type* DX breast cancer test. We have also received a limited number of approvals from other state Medicaid programs.

The majority of our international Onco*type* DX breast cancer test revenues come from patient self-pay, payor reimbursement through our distributor in Israel and clinical collaborations in various countries. We have exclusive distribution agreements for our Oncotype DX breast cancer test with distributors in 13 countries outside of the United States, and have established reimbursement arrangements with several public and private payors and hospitals. We have obtained coverage for our test in Canada, Ireland, Germany, Greece, Israel and the United Kingdom. We expect that it will take several years to establish broad coverage and reimbursement for our Onco*type* DX breast cancer test with payors in countries outside of the United States.

Oncotype DX Colon Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Onco*type* DX colon cancer test, which we launched in January 2010. We believe the key factors that will drive adoption of this test include publication of peer-reviewed articles on the QUASAR clinical validation study and other studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia and our ongoing commercial efforts. We are working with public and private payors and health plans to secure coverage for our colon cancer test based upon clinical evidence showing the utility of the test. We may need to hire additional commercial, scientific, technical and other personnel to support this process.

We have obtained limited reimbursement coverage from third-party payors for our Onco*type* DX colon cancer test. As a new test, our colon cancer test may be considered investigational by payors and therefore may not be covered under their reimbursement policies. Consequently, we intend to pursue case-by-case reimbursement and expect that this test will continue to be reviewed on this basis until policy decisions have been made by individual payors. We are also working with public and private payors and health plans to secure coverage for our Onco*type* DX colon cancer test based upon clinical evidence showing the utility of the test. We believe it may take several years to achieve reimbursement with a majority of third-party payors for our colon cancer test. However, we cannot predict whether, or under what circumstances, payors will reimburse for this test.

Payment and Coding

Clinical laboratory testing services, when covered by third-party payors, are paid under various methodologies, including prospective payment systems and fee schedules. Under Medicare in the United States, 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 adjusted annually, based upon a formula that incorporates the annual change in the consumer price index, or CPI, for the prior year as well as other factors. 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.

Table of Contents

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 the Onco*type* DX breast or colon cancer tests. The tests are reported under a non-specific, unlisted procedure code, which is subject to manual review of each claim. With regard to Medicare s current reimbursement of our Onco*type* DX breast cancer test, we were informed that, under the local coverage determination, claims are to be paid consistent with the average allowed reimbursement rate for claims that were billed and processed to completion as of September 30, 2005. This reimbursement rate remains in effect as of the date of this report, but is subject to review and adjustment.

A Healthcare Common Procedure Coding System, or HCPCS, code has been issued effective January 1, 2006 for the Onco*type* DX breast cancer test that some private third-party payors in the United States may accept on claims for the test. However, Medicare will not accept this HCPCS code. The American Medical Association, which has the copyright on the CPT coding system, has announced the formation of a Molecular Pathology Work Group charged with developing a new coding framework for non-infectious disease molecular pathology testing and recommending new codes to the CPT Editorial Panel, which determines new and revised codes and descriptors. It is possible that The Molecular Pathology Work Group will propose and the CPT Editorial Panel will adopt a new code or codes to report Onco*type* DX tests, and these codes could result in higher or lower reimbursement rates for our tests. Whether or not we obtain a specific CPT code for our tests, there can be no assurance that an adequate payment rate will continue to be assigned to the tests.

On several occasions, including negotiations over the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 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, these additional co-insurance payments for our Onco*type* DX tests could be difficult to collect.

Competition

We believe that we compete primarily on the basis of:

- the value of the quantitative information our Onco*type* DX platform provides;
- the clinical validation of our Onco*type* DX breast cancer test s ability to predict recurrence and survival, and demonstration of its ability to predict the likelihood of chemotherapy benefit;
- the level of reimbursement coverage for our Onco*type* DX breast cancer test;
- the inclusion of our Onco*type* DX breast cancer test in clinical practice guidelines.
- the clinical validation of our Onco*type* DX colon cancer test s ability to predict recurrence and survival;
- our ability to perform clinical studies using archival tissue as it is currently processed, handled and stored;
- our ability to screen thousands 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; and

our ability to obtain appropriate regulatory approvals in a timely fashion.

Table of Contents

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 our Onco*type* DX tests will not be introduced. We believe that our continued success depends on our ability to:

- continue to innovate and maintain scientifically advanced technology;
- successfully market and sell our Onco*type* DX tests;
- enhance our Onco*type* DX tests to provide information in response to additional indications;
- continue to validate our tests, especially with respect to chemotherapy benefit;
- continue to obtain positive reimbursement decisions from payors;
- expand our Onco*type* DX platform for use in types of cancer other than breast and colon;
- continue to expand in countries outside of the United States;
- attract and retain skilled personnel;
- obtain patents or other protection for our products and technology; and
- obtain and maintain our clinical reference laboratory accreditations and licenses.

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

We also face competition from companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast or colon cancer, including public companies such as Celera Corporation, GE Healthcare, a business unit of General Electric Company, Hologic, Inc., Novartis AG, Myriad Genetics, Inc., Qiagen N.V. and Response Genetics, Inc., and many private companies. We face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding, Ltd, Siemens AG 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. Additionally, projects related to cancer genomics have received increased government funding, both in the United States and internationally. 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 that these products may compete with ours. In addition, competitors may develop their own versions of our tests 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 Onco*type* DX tests are considered relatively expensive for diagnostic tests. We have changed the list price of our breast cancer test in the past and we may change prices for our tests in the future. Any increase or decrease in pricing could impact reimbursement of and demand for our tests. 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 tests, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve sustained profitability. Some competitors have developed tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than Onco*type* DX tests, and that may discourage adoption and reimbursement of our tests. 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 tests, which could prevent us from increasing or

Table of Contents

sustaining our revenues or achieving sustained profitability and could cause the market price of our common stock to decline.

Regulation

United States

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 current 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 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 tests 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

Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. 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 our Onco*type* DX tests 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 the FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use, which are referred to as 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 our Onco*type* DX tests are not diagnostic kits and also believe that they are LDTs. As a result, we believe our tests 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 regulation but is currently exempt from pre-market review by the FDA.

In January 2006, we received a letter from the FDA regarding our Onco*type* DX breast cancer test inviting us to meet with the 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, the FDA issued draft guidance

on a new class of tests called In Vitro Diagnostic Multivariate Index Assays , or IVDMIAs. Under this draft guidance, our Onco*type* DX tests 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, the FDA posted revised draft guidance that addressed some of the comments submitted in response to the September 2006 draft guidance. The revised draft guidance included a transition period of FDA enforcement discretion of up to 18 months 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. It is

unclear whether the FDA will ever issue final guidance on IVDMIAs or withdraw the draft guidance that was issued in 2007.

In May 2007, the 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, the 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 PMAs, 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 June 2010, the FDA announced a public meeting to discuss the agency s oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision making and disease management, particularly in the context of personalized medicine. The FDA indicated that it is considering a risk-based application of oversight to LDTs and that, following public input and discussion, it may issue separate draft guidance on the regulation of LDTs which may vary from the previously issued draft guidance on the regulation of IVDMIAs. The public meeting was held in July 2010 and further public comments were submitted to the FDA in September 2010. In November 2010, at a public meeting with the laboratory industry, an FDA spokesperson indicated that the agency had prepared draft guidance regarding proposed oversight of LDTs which was under review for possible issuance.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through additional guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. Legislative proposals addressing oversight of genetic testing and LDTs were introduced in the previous two Congresses and we expect that new legislative proposals will be introduced in the current Congress that convened in January 2011. It is possible that legislation could be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or develop and introduce new 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.

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 the FDA could require that we stop selling our tests pending pre-market clearance or approval. If our tests are allowed to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA, or if labeling claims the 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 the FDA. If pre-market review is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by the FDA and to the requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

Should any of the reagents obtained by us from vendors and used in conducting our tests 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

Table of Contents

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.

However, we cannot 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 assurance that we will be found to be in compliance with these laws following any such regulatory review.

Table of Contents

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 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 do 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

Table of Contents

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, making a false record or statement in order to secure payment or retaining an overpayment 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.

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 reference 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, under New York 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.

We maintain such licensure for our clinical reference laboratory for our Onco*type* DX tests. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such

Table of Contents

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 the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory s operator 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 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.

International

When marketing our tests outside of the United States, we are subject to foreign regulatory requirements governing human clinical testing, export of tissue 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. We are also required to maintain accurate information and control over sales and distributors activities that may fall within the purview of the Foreign Corrupt Practices Act, its books and records provisions and its anti-bribery provisions.

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 unpatented 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, 2010, we had 11 issued patents in the United States and 12 issued patents outside of the United States covering genes and methods that are components of the Onco*type* DX breast cancer test, six of which were issued jointly to us and our collaborators, and three of which were assigned to us by a collaborator. In addition, we have a number of pending patent applications in the United States and in other countries, including provisional and non-provisional filings. Our issued U.S. patents expire at various times between 2024 and 2026. 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

Table of Contents

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 some 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 to strengthen our intellectual property rights. Our pending and future patent applications may not result in issued patents, and we cannot assure you that our issued patents or any patents that might ultimately be issued by the U.S. Patent and Trademark Office, or USPTO, will protect our technology. Any patents issued to United States 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 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 and 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. We may also initiate claims to defend our intellectual property. Assertions of misappropriation, infringement or misuse, or actions seeking to establish the validity of our patents could 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 our Onco*type* DX tests or other 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 proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling 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 PCR, homogeneous polymerase chain reaction, and RT-PCR. We use these

processes in our research and development activities and in the processing of our Onco*type* DX tests. The Roche license is limited to clinical laboratory services performed 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

Table of Contents

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 activities 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 product revenues.

Research and Development Expenses

Research and development expenses were $33.2 million, $35.7 million and $28.6 million for the years ended December 31, 2010, 2009, and 2008, respectively. During 2010, we continued to conduct research and development studies in breast cancer, colon cancer and other cancers.

Employees

As of December 31, 2010, we had 472 employees, including 87 in clinical reference laboratory operations, 99 in research and development, including bioinformatics, 169 in sales and marketing, 60 in information technology and systems and 57 in general and administrative functions. 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 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 have a history of net losses, we may incur net losses in the future, and we expect to continue to incur significant expenses to develop and market our tests, which may make it difficult for us to achieve sustained profitability.

We have historically incurred substantial net losses. From our inception in August 2000 through December 31, 2010, we had an accumulated deficit of $173.6 million. We expect to continue to invest in our product pipeline, including our current Onco*type* DX tests and future products, and our commercial and laboratory infrastructure. For the year ended December 31, 2010, our research and development expenses were $33.2 million and our sales and marketing expenses were $71.4 million. We expect our expense levels to continue to increase for the foreseeable future as we seek to expand the clinical utility of our Onco*type* DX breast cancer test, drive adoption of and reimbursement for our Onco*type* DX colon cancer test and develop new tests. As a result, we will need to generate significant revenues in

order to achieve sustained profitability. Our failure to achieve sustained profitability in the future could cause the market price of our common stock to decline.

Continued weak general economic or business conditions could have a negative impact on our business.

Continuing concerns over prolonged high unemployment levels across the United States, the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget proposals, inflation, deflation,

Table of Contents

taxation issues, energy costs and geopolitical issues have contributed to increased volatility and diminished expectations for the U.S. economy. These factors, combined with declines in business and consumer confidence and a volatile stock market, have precipitated an economic slowdown and expectations of slower economic growth going forward. The economic slowdown continued to have a negative impact on growth in tests delivered during the year ended December 31, 2010, particularly in areas of the United States with high unemployment levels where patients have lost healthcare coverage, delayed medical checkups or are unable to pay for our tests. If the economic environment does not improve or deteriorates, 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.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and results of operations.

The recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, which makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, each medical device manufacturer will have to pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. Although there are some exceptions, because the FDA maintains that clinical laboratory tests that are developed and validated by a laboratory for its own use, or LDTs, such as our Onco*type* DX breast and colon cancer tests, are medical devices, this tax may apply to some or all of our current products and products in development. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. This adjustment is in addition to a productivity adjustment to the Medicare Clinical Laboratory Fee Schedule. These reductions in payments may apply to some or all of our clinical laboratory test services furnished to Medicare beneficiaries.

Other significant measures contained in the PPACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, lowering the government s thresholds to find violations and increasing potential penalties for such violations. In addition, the PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative impact on payment rates for services, including clinical laboratory services. IPAB proposals may impact payments for clinical laboratory services beginning in 2016 and for hospital services beginning in 2020.

In addition to the PPACA, the effect of which cannot presently be fully quantified given its recent enactment, various healthcare reform proposals have also emerged at the state level. Changes in healthcare policy, such as changes in the FDA regulatory policy for LDTs, the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management s attention from our business. In addition, sales of our tests outside of the United States make us subject to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government s role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations, possibly materially.

29

Table of Contents

If third-party payors, including managed care organizations and Medicare, do not provide reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our Oncotype DX tests, our commercial success could be compromised.

Physicians and patients may not order our Onco*type* DX tests 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.

There is uncertainty concerning third-party payor reimbursement of any test incorporating new technology, including tests developed using our Onco*type* DX platform. Several entities conduct technology assessments of new 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 our Onco*type* DX breast cancer test, the test has received negative assessments in the past and our tests may receive negative assessments in the future. For example, in April 2010, the Medical Advisory Panel of the Blue Cross and Blue Shield Association s Technology Evaluation Center, a technology assessment group, published its conclusion that the existing clinical data in support of our Onco*type* DX breast cancer test did not meet the panel s technology criteria for clinical effectiveness and appropriateness for usage in patients with N+ disease.

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 positive coverage determinations for our Onco*type* DX breast cancer test for N-, ER+ patients from most third-party payors in the United States through contracts, agreements or policy decisions. We cannot be certain that coverage for this test will be provided in the future by additional third-party payors or that existing contracts, agreements or policy decisions or reimbursement levels will remain in place or be fulfilled within existing terms and provisions.

Following the reporting of clinical studies to support the use of our Onco*type* DX breast cancer test in patients with N+, ER+ disease, we experienced an increase in usage for N+ patients. We may not be able to obtain reimbursement coverage for our test for breast cancer patients with N+, ER+ disease that is similar to the coverage we have obtained for early stage N-, ER+ patients.

We have obtained limited reimbursement coverage from third-party payors in the United States for our Onco*type* DX colon cancer test launched in January 2010. We expect to focus substantial resources on obtaining adoption of and reimbursement coverage for this test. Because it is new, our Onco*type* DX colon cancer test may be considered investigational by payors and therefore may not be covered under their reimbursement policies. We believe it may take several years to achieve reimbursement with a majority of third-party payors. However, we cannot predict

whether, under what circumstances, or at what payment levels payors will reimburse for our test. If we fail to establish broad adoption of and reimbursement for our Onco*type* DX colon cancer test, our reputation could be harmed and our future prospects and our business could suffer.

If we are unable to obtain reimbursement from private payors and Medicare and Medicaid programs for our tests or new tests or test enhancements we may develop in the future, our ability to generate revenues could be limited. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third-party payors due to contract implementation steps, documentation requirements and other issues, which could cause our revenues to fluctuate from period to period.

Table of Contents

The prices at which our tests are reimbursed may be reduced by Medicare and private and other payors, and any such changes could have a negative impact on our revenues.

Even if we are being reimbursed for our tests, Medicare and private and other payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests, which would reduce our total revenues. In addition, 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 healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the clinical laboratory industry. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in the reimbursement rate of payors may occur in the future. Reductions in the prices at which our tests are reimbursed could have a negative impact on our revenues.

There is no specific Current Procedural Terminology, or CPT, procedure code or group of codes to report the Onco*type* DX breast or colon cancer tests. The tests are reported under a non-specific, unlisted procedure code, which is subject to manual review of each claim. With regard to Medicare s current reimbursement of our Onco*type* DX breast cancer test, we were informed that, under the local coverage determination, claims are to be paid consistent with the average allowed reimbursement rate for claims that were billed and processed to completion as of September 30, 2005. This reimbursement rate remains in effect as of the date of this report, but is subject to review and adjustment.

A Healthcare Common Procedure Coding System, or HCPCS, code has been issued effective January 1, 2006 for the Onco*type* DX breast cancer test that some private third-party payors may accept on claims for the test. However, Medicare will not accept this HCPCS code. The American Medical Association, which has the copyright on the CPT coding system, has recently established a work group to develop a new coding framework for non-infectious disease molecular pathology testing and recommend new codes to the panel, which determines new and revised codes and descriptors. It is possible that this process will result in a new code or codes to report our Onco*type* DX tests, and the codes may result in higher or lower reimbursement of our tests. Whether or not we obtain a specific CPT code for our tests, there can be no assurance that an adequate payment rate will continue to be assigned to the tests, which could have a negative impact on our revenues.

If we are unable to obtain or maintain adequate reimbursement for our tests outside of the United States, our ability to expand internationally will be compromised.

The majority of our international product revenues are currently generated by patient self-pay and third party reimbursement for our Onco*type* DX breast cancer test and through clinical collaborations. In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. We expect that it will take several years to establish broad coverage and reimbursement for our tests with payors in countries outside of the United States, and our efforts may not be successful. In addition, because we rely on distributors to obtain reimbursement for our tests, to the extent we do not have direct reimbursement arrangements with payors, we may not be able to retain reimbursement coverage with a particular payor if our agreement with a distributor is terminated or expires.

Because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.

Under current Medicare billing rules, claims for our Onco*type* DX breast cancer 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 to purchase these tests, we may not be paid for our tests or may have to pursue payment from the hospital on a

Table of Contents

case-by-case basis. We believe patients coming under this rule represent approximately 1% of our total breast cancer testing population. We believe these billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our breast cancer test, and could discourage Medicare patients from using our test. If we obtain Medicare reimbursement coverage for our Onco*type* DX colon cancer test in the future, these billing rules would also apply to those tests performed for hospital inpatients ordered less than 14 days from discharge. We have no assurance that Medicare will reverse or revise the billing rule to allow us to bill for tests subject to the 14 day billing rule or that Congress will require Medicare to do so at some point in the future, and we also cannot ensure that hospitals will agree to arrangements to pay us for Onco*type* DX tests performed on patients falling under these rules.

We depend on Medicare for a significant portion of our product revenues and if Medicare or other significant payors stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenues could decline.

Reimbursement on behalf of patients covered by Medicare accounted for 21%, 20% and 22% of our product revenues for the years ended December 31, 2010, 2009, and 2008, respectively. While there were no other third-party payors with product revenues of 10% or more for these periods, there have been in the past, and may be in the future, other payors accounting for 10% or more of our product revenues. Because the majority of stage II colon cancer patients in the United States are age 65 and over, we may become more dependent on Medicare reimbursement in the future. It is possible that Medicare or other third-party payors that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

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

For the near future, we expect to derive substantially all of our revenues from sales of one test, our Onco*type* DX breast cancer test. We have been selling this test since January 2004. While we launched our test for colon cancer in January 2010, we do not expect to recognize significant revenues from this test until adoption of and reimbursement for this test have been established. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing tests. We may not be able to successfully commercialize tests for other cancers or diseases. If we are unable to increase sales of our breast cancer test, establish adoption of and reimbursement for our colon cancer test, or successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve sustained profitability would be impaired.

If the FDA were to begin regulating our tests, 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 tests.

Clinical laboratory tests like ours are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as administered by the Centers for Medicare and Medicaid Services, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. 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 our Onco*type* DX tests are not diagnostic kits and also believe that they are LDTs. As a result, we believe our tests 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 the FDA.

At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through additional guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. Legislative proposals addressing oversight of genetic testing and LDTs were introduced in the previous two Congresses and we expect that new legislative proposals will be introduced in the current Congress as well. It is

Table of Contents

possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new 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.

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 the FDA could require that we stop selling our tests pending pre-market clearance or approval. If our tests are allowed to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are very 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 pre-market approval application with the FDA. If pre-market review is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by and the requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

Should any of the reagents obtained by us from vendors and used in conducting our tests 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 our breast and colon cancer tests or any other tests we may develop, those trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and interruption in sales of our current tests and harm our ability to achieve sustained profitability.

If the FDA decides to regulate our tests, it may require additional pre-market clinical testing prior to submitting a regulatory notification or 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 of any future tests and interrupt sales of our current tests. 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 tests. 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 tests, or to achieve sustained profitability.

Table of Contents

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 through our accreditation by the College of American Pathologists, or CAP. 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.

Although we are required to hold a certificate of accreditation under CLIA that allows us to perform high complexity testing, we are not required to hold a certificate of accreditation through CAP. We could alternatively maintain a certificate of accreditation from another accrediting organization or a certificate of compliance through inspection by surveyors acting on behalf of the CLIA program. If our accreditation under CAP were to terminate, either voluntarily or involuntarily, we would need to convert our certification under CLIA to a certificate of compliance (or to a certificate of accreditation with another accreditation organization) in order to maintain our ability to perform clinical testing and to continue commercial operations. Whether we would be able to successfully maintain operations through either of these alternatives would depend upon the facts and circumstances surrounding termination of our CAP accreditation, such as whether any deficiencies were identified by CAP as the basis for termination and, if so, whether these were addressed to the satisfaction of the surveyors for the CLIA program (or another accrediting organization).

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. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York State. 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. Moreover, several other 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 tests.

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 our tests, which would limit our revenues and harm our business. If we were to lose our license in New York or 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 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 False Claims Act civil and criminal penalties 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

Table of Contents

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.

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

We have multiple tests in development and devote considerable resources to research and development. For example, we are conducting early development studies in colon cancer for stage III patients, prostate, renal cell and lung cancers. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of cancers other than breast and colon cancer with the sensitivity and specificity necessary to be clinically and commercially useful, or that our colon cancer test will result in a commercially successful product. In addition, before we can develop diagnostic tests for new cancers or other diseases 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.

This product development process involves a high degree of risk and may take 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 might choose to abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business. In addition, competitors may develop and commercialize competing products faster than we are able to do so.

If we are unable to support demand for our tests, including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer.

As our test volume grows, we will need to continue to ramp up our testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements, and expand our internal quality assurance program, technology and manufacturing platforms 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, technology, 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

Table of Contents

scale our commercial operations will not negatively affect the quality of our 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 our tests, 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 tests.

If medical practitioners do not order our Onco*type* DX tests 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 achieve sustained profitability. To generate demand, we will need to continue to make oncologists, surgeons and pathologists aware of the benefits of each type of test 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 and maintain adequate reimbursement coverage from third-party payors.

Prior to the inclusion of our Onco*type* DX breast cancer test in clinical guidelines, guidelines and practices regarding the treatment of breast cancer 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 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 our test for their patients, which could limit our ability to generate revenues and achieve sustained profitability.

Our Onco*type* DX colon cancer test predicts recurrence but, unlike our breast cancer test, does not predict chemotherapy benefit. We will need to educate physicians, patients and payors about the benefits and cost-effectiveness of our colon cancer test and to establish reimbursement arrangements for this test with payors. We may need to hire additional commercial, scientific, technical and other personnel to support this process. If our marketing and educational efforts do not result in sufficient physician or patient demand, we may not be able to obtain adequate reimbursement for our colon cancer test. If we fail to successfully establish adoption of and reimbursement for our colon cancer test, our reputation could be harmed and our business could suffer.

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

Some patients may decide not to use our Onco*type* DX tests due to their price, all or part 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 tests, patients may still decide not to use our tests, 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 environment could continue to negatively impact patients, resulting in loss of healthcare coverage, delayed medical checkups or inability to pay for relatively expensive tests. If only a small portion of the patient population decides to use our tests, we will experience limits on our revenues and our ability to achieve sustained profitability.

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 tests. 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

margins on our tests. We may need to license other technologies 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

Table of Contents

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.

If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could 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 tissue specimens. New chemotherapeutic or biologic strategies are being developed that may increase survival time and reduce toxic side effects. There have also been advances in methods used to analyze very large amounts of genomic information, including next-generation sequencing. These advances require us to continuously develop our technology, develop new products and enhance existing products to keep pace with evolving standards of care. Our tests could become obsolete unless we continually innovate and expand our products 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 tests to new treatments, sales of our test could decline, which would harm our revenues.

If we are unable to maintain intellectual property protection, our competitive position could be harmed.

Our ability to compete and to achieve sustained profitability is impacted by our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of 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 we cannot guarantee that a joint owner will cooperate with us in the enforcement of patent rights.

As of December 31, 2010, we had 11 issued patents in the United States and 12 issued patents internationally covering genes and methods that are components of the Onco*type* DX breast cancer test, six of which were issued jointly to us and our collaborators and three of which were assigned to us by a collaborator. In addition, we have a number of pending patent applications in the United States and in other countries. Our pending patent applications may not result in issued patents, and we cannot assure you that our issued patents or any patents that might ultimately be issued by the U.S. Patent and Trademark Office, or USPTO, 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 U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO 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.

On October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U.S. Supreme Court reversed that decision in 2010, finding that the machine-or-transformation test is not the only test for determining patent

eligibility. The Court, however, declined to specify how and when processes are patentable. In response, the USPTO issued an Interim Guidance for Determining Subject Matter Eligibility for Process Claim dated July 27, 2010. We cannot assure you that our patent portfolio will not be negatively impacted by the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics and the USPTO, could also impact biotechnology patents. That case involves certain of Myriad s

Table of Contents

U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. Related European patents were canceled in 2004 by the European Patent Office after opposition, and a similar challenge is pending in Australia. The plaintiffs in the Myriad case filed motions for summary judgment in the Southern District of New York requesting that the court, among other things, find that the breast cancer genes are not patentable subject matter. We joined other diagnostic companies in filing an *amici* brief in this case. The U.S. District Court for the Southern District of New York filed an opinion on this case on March 20, 2010, finding that Myriad s BRCA sequence and sequence related claims are unpatentable under the Federal Circuit machine or transformation test. This case is currently pending before the Federal Circuit, which has been instructed by the Supreme Court to use broader patentability principles. It is unknown how this case will be decided on appeal, whether this decision will have an indirect impact on gene patents generally, or if this decision will have a significant impact on the ability of biotechnology companies to obtain or enforce gene patents in the future.

Also, on February 5, 2010, the Secretary s Advisory Committee on Genetics, Health and Society for HHS voted to approve a report entitled Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. That report defines patent claims on genes broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. In addition, the report recommended that the Secretary should explore, identify, and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote non-exclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether these recommendations will be acted upon by the HHS, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future research and development efforts.

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 and 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 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 or to seek relief on allegations that we use, sell, or offer to sell technology that incorporates third party 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 tests 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 tests to include the non-infringing technologies would require us to re-validate our tests, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our tests. Parties making infringement claims on future issued patents may be able to obtain an injunction that could prevent us from selling our tests 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.

Table of Contents

If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve sustained 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 ours that are performed outside the pathology laboratory. In addition, few diagnostic methods are as expensive as our Onco*type* DX tests.

We also face competition from companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast or colon cancer, including public companies such as Celera Corporation, GE Healthcare, a business unit of General Electric Company, Hologic, Inc., Novartis AG, Myriad Genetics, Inc., Qiagen N.V. and Response Genetics Inc., and many private companies. We face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding Ltd, Siemens AG 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. Additionally, projects related to cancer genomics have received increased government funding, both in the United States and internationally. 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 tests 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 have changed the list price of our breast cancer test in the past and we may change prices for our tests in the future. Any increase or decrease in pricing could impact reimbursement of and demand for our tests. 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 tests, which could force us to lower the list prices of our tests and impact our operating margins and our ability to achieve sustained profitability. Some competitors have developed tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than Onco*type* DX tests, and that may discourage adoption of and reimbursement for our tests. 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 tests, which could prevent us from increasing or sustaining our revenues or achieving sustained 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, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, 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.

Table of Contents

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 the contracted 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 agreements on acceptable terms, we would be required to seek alternatives. 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, the National Surgical Adjuvant Breast and Bowel Project, or 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 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 collaboration agreement or the entity s announcement of a collaboration with an entity other than us could 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 transition to a company with multiple commercialized products. 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 competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. In addition, it is expected that there will be a shortage of clinical laboratory scientists in coming years, which would make it more difficult to hire sufficient numbers of qualified personnel. 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 could adversely affect our ability to support our research and 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.

Table of Contents

If our sole laboratory facility becomes inoperable, we will be unable to perform our tests 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, if at all.

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 tests 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 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 considerable 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 licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to begin operations.

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

Our business strategy incorporates international expansion, including establishing and maintaining direct sales and physician outreach and education capabilities outside of the United States and expanding our relationships with distributors. 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 tests in various countries;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes or patient self-pay systems;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to process tests locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;

natural disasters, 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.

Table of Contents

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 foreign sales of our Oncotype DX tests could limit or prevent us from selling our test in foreign markets and from realizing long-term international revenue growth.

As of December 31, 2010, we had exclusive distribution agreements for our Onco*type* DX breast cancer test in 13 countries outside of the United States, 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 our test. Distributors may not commit the necessary resources to market and sell our test 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, form joint ventures or make investments in other companies or technologies 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 in 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, or make investments in other companies. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of 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 experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions 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, joint venture or investment.

To finance any acquisitions or investments, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. Periods of upheaval in the capital markets and world economy have in the past, and may in the future, cause volatility in the market price of our common stock. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. 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, similar types of investments have in the past and may in the future experience losses in value or liquidity issues which differ from historical patterns. 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.

Table of Contents

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

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 Onco*type* DX tests and enhancements to those tests;
- fund commercialization of any future tests we may develop;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- further expand our clinical laboratory operations;
- expand our technologies into other areas of cancer or other diseases;
- expand our research and development activities;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

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

- the rate of progress in establishing reimbursement arrangements with domestic and international 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 our Onco*type* DX breast and colon cancer tests;
- the rate of progress and cost of selling and marketing activities associated with establishing adoption of and reimbursement for our Onco*type* DX colon cancer test;
- the rate of progress and cost of research and development activities associated with products in research and early development focused on cancers other than breast and colon 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;

the impact of changes in Federal, state and international taxation; and

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

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. The terms of debt securities issued or borrowings 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

Table of Contents

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 more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. 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 could lower the economic value of those programs to our company.

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.

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, or those materials do not meet our quality specifications.

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 our Onco*type* DX platform. 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 we require for our tests, we may need to reconfigure our test processes, 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, or if the materials do not meet our quality specifications, delays in commercialization or an interruption in sales could occur.

We may be unable to manage our future growth effectively, which could 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 may 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.

Table of Contents

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 tests could lead to the filing of product liability claims if someone were to allege that our tests 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 our Onco*type* DX breast cancer test for patients who do not have the same specific clinical attributes indicated on the 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 our test for such patients, including patients with ER- breast cancers. 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 clinical partners to terminate existing agreements and potential clinical partners 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 become significant and could negatively affect our operating results.

We must implement additional and expensive 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.

We are subject to increasingly complex taxation rules and practices, which may affect how we conduct our business and our results of operations.

As our business grows, we are required to comply with increasingly complex taxation rules and practices. We are subject to tax in multiple U.S. tax jurisdictions and in foreign tax jurisdictions as we expand internationally. The development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in, or interpretations of, tax rules and regulations in the jurisdictions in which we do business, by lapses of the availability of the U.S. research and development tax credit or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that involve significant judgment. We are subject to the examination of our tax returns by federal, state

Table of Contents

and foreign tax authorities, which could focus on our intercompany transfer pricing methodology as well as other matters. If our tax strategies are ineffective or we are not in compliance with domestic and international tax laws, our financial position, operating results and cash flows could be adversely affected.

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

None.

ITEM 2. ***Properties***.

At December 31, 2010, we leased approximately 126,500 square feet of laboratory and office space in Redwood City, California under operating leases that expire between March 2018 and March 2019, with options for us to extend the term of each lease for an additional five years. We also leased approximately 2,500 square feet of office space in Geneva, Switzerland under an operating lease that expires in May 2015. 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 material legal proceedings at December 31, 2010, or at the date of this report.

ITEM 4. ***(Removed and Reserved).***

Executive Officers of the Registrant

The names of our executive officers and their ages as of March 1, 2011, are as follows:

Name	Age	Position
Randal W. Scott, Ph.D.	53	Executive Chairman of the Board
Kimberly J. Popovits	52	President and Chief Executive Officer and Director
G. Bradley Cole	55	Chief Operating Officer; Secretary
Steven Shak, M.D.	60	Chief Medical Officer
Joffre B. Baker, Ph.D.	63	Chief Scientific Officer
Dean L. Schorno	48	Chief Financial 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 since January 2009, and also served as Chief Financial Officer from July 2004 until January 2011. Prior to that, Mr. Cole served as Executive Vice President, Operations from January 2008 and as Executive Vice President and Chief Financial Officer from July 2004 until January 2009. Mr. Cole has also served as Secretary since February 2005. From December 1997 to May 2004, he served in various roles 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

Table of Contents

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 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.

Dean L. Schorno has served as our Chief Financial Officer since January 2011, Senior Vice President, Finance from February 2010, Vice President, Finance from August 2008 until February 2010, and as Vice President, Operations from January 2004 until August 2008. From July 2001 through December 2003, he led the Company s finance group as a Director and then Senior Director. Before joining Genomic Health, from 1991 through 2001, Mr. Schorno headed an accounting and consulting firm, which he founded. From 1985 to 1991, Mr. Schorno worked at an international accounting firm. Mr. Schorno holds a B.S in Business Administration from the University of California, Berkeley and is a Certified Public Accountant.

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 per share, 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:

	2010			
	First Quarter	**Second Quarter**	**Third Quarter**	**Fourth Quarter**
Stock price high	$ 20.15	$ 17.75	$ 15.45	$ 23.72
Stock price low	$ 16.20	$ 12.83	$ 11.94	$ 13.13

	2009			
	First Quarter	**Second Quarter**	**Third Quarter**	**Fourth Quarter**

Stock price	high	$ 25.16	$ 27.22	$ 22.00	$ 21.73
Stock price	low	$ 18.63	$ 16.25	$ 15.81	$ 18.29

According to the records of our transfer agent, we had 85 stockholders of record as of February 28, 2011.

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 any future earnings 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.

Table of Contents

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 December 31, 2005 in each of our common stock, the NASDAQ Market Index and the NASDAQ Biotechnology Index for the period commencing on December 31, 2005 and ending on December 31, 2010. 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 NASDAQ BIOTECHNOLOGY INDEX

	December 31, 2005	December 31, 2006	December 31, 2007	December 31, 2008	December 31, 2009	December 31, 2010
Genomic Health, Inc.	$ 100.00	$ 204.17	$ 248.52	$ 213.83	$ 214.71	$ 234.80
NASDAQ Market Index	$ 100.00	$ 111.74	$ 124.67	$ 73.77	$ 107.12	$ 125.93
NASDAQ Biotechnology Index	$ 100.00	$ 99.71	$ 103.09	$ 96.34	$ 106.49	$ 114.80

Table of Contents

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, 2010 and 2009 and the selected consolidated statements of operations data for each year ended December 31, 2010, 2009 and 2008 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, 2008, 2007 and 2006 and the selected consolidated statements of operations data for each year ended December 31, 2007 and 2006 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,				
	2010	2009	2008	2007	2006
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product revenues	$ 174,870	$ 146,581	$ 108,658	$ 62,745	$ 27,006
Contract revenues	3,231	2,967	1,921	1,282	2,168
Total revenues	178,101	149,548	110,579	64,027	29,174
Operating expenses(1):					
Cost of product revenues	34,634	32,562	27,185	17,331	9,908
Research and development	33,225	35,691	28,624	22,053	12,841
Selling and marketing	71,405	61,132	46,668	36,456	24,625
General and administrative	34,913	29,564	25,617	17,849	12,765
Total operating expenses	174,177	158,949	128,094	93,689	60,139
Income (loss) from operations	3,924	(9,401)	(17,515)	(29,662)	(30,965)
Interest and other income, net	228	550	1,365	2,370	2,045
Income (loss) before income taxes	4,152	(8,851)	(16,150)	(27,292)	(28,920)
Income tax expense (benefit)	(136)	560	(61)		
Net income (loss)	$ 4,288	$ (9,411)	$ (16,089)	$ (27,292)	$ (28,920)
Basic net income (loss) per share	$ 0.15	$ (0.33)	$ (0.57)	$ (1.02)	$ (1.18)
Diluted net income (loss) per share	$ 0.14	$ (0.33)	$ (0.57)	$ (1.02)	$ (1.18)
Weighted-average shares used in computing basic net income (loss) per share	28,815	28,563	28,298	26,760	24,509
	29,653	28,563	28,298	26,760	24,509

Weighted-average shares used in computing diluted net income (loss) per share

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

	Year Ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands)				
Cost of product revenues	$ 342	$ 364	$ 491	$ 375	$ 167
Research and development	2,881	3,098	2,913	1,882	821
Selling and marketing	3,086	3,171	2,622	1,876	779
General and administrative	4,035	3,522	3,112	2,152	1,137
Total	$ 10,344	$ 10,155	$ 9,138	$ 6,285	$ 2,904

Table of Contents

	2010	2009	At December 31, 2008	2007	2006
			(In thousands)		
Consolidated Balance Sheets Data:					
Cash, cash equivalents and short-term investments	$ 76,818	$ 57,448	$ 56,670	$ 68,360	$ 44,215
Working capital	76,097	55,541	52,693	63,948	37,516
Total assets	110,861	88,107	86,689	87,929	58,024
Notes payable		225	2,039	4,726	7,273
Accumulated deficit	(173,607)	(177,895)	(168,484)	(152,395)	(125,103)
Total stockholders equity	86,110	68,509	66,175	71,166	41,829

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 molecular diagnostic company focused on the development and global commercialization of genomic-based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. In January 2004, we launched our first Onco*type* DX test, which is used to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit in early stage breast cancer patients. Effective June 1, 2010, the list price of our Onco*type* DX breast cancer test increased from $3,975 to $4,075. In January 2010, we launched our second Onco*type* DX test, which is used to predict the likelihood of cancer recurrence in stage II colon cancer patients. The list price for our Onco*type* DX colon cancer test is $3,200. Substantially all of our historical revenues have been derived from the sale of Onco*type* DX breast cancer tests ordered by physicians in the United States.

For the year ended December 31, 2010, more than 57,270 Onco*type* DX test reports were delivered for use in treatment planning, compared to more than 49,030 and 39,640 test reports delivered for the years ended December 31, 2009 and 2008, respectively. All of our tests are conducted at our clinical reference laboratory in Redwood City, California. Our clinical reference laboratory processing capacity is currently approximately 18,000 tests per calendar quarter. As test processing for our Onco*type* DX breast and colon cancer tests is essentially the same, except that the tests use different RNA extraction methods and analyze different genes, we believe that we currently have sufficient capacity to process both of our tests.

We depend upon third-party payors to provide reimbursement for our tests. Accordingly, we have and expect to continue to focus substantial resources on obtaining reimbursement coverage from third-party payors.

We have also continued to expand our business, both in the United States and internationally. We plan to continue to use essentially the same business model internationally as we use in the United States, however, there are significant differences between countries that need to be considered. For example, different countries may have a public healthcare system, a combination of public and private healthcare system or a cash-based payment system. Our initial commercialization efforts in markets outside of the United States have focused on offering products on a patient

self-pay basis and, over time, seeking coverage from public health systems and private insurance on a country by country basis. We have sales representatives in certain countries outside of the United States. We may decide to work directly on our own in certain countries while continuing to utilize distributors in other countries. We established a European subsidiary in February 2009 and have lead executives with assignments in the Americas, Europe and Asia to support our international efforts.

We expect that international sales of our Onco*type* DX tests will be heavily dependent on the availability of reimbursement. 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

Table of Contents

so, how much will be paid. We expect that it will take several years to establish broad coverage and reimbursement for our tests in countries outside of the United States, and we do not expect international product revenues to comprise more than 10% of our total revenues until the second half of 2011.

Oncotype DX Breast Cancer Test

We believe increased demand for our Onco*type* DX breast cancer test resulted from our ongoing commercial efforts, continued publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia, and the inclusion of our breast cancer test in clinical practice guidelines. However, this increased demand is not necessarily indicative of future growth rates, 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 our breast cancer test in the future. Sequential quarterly demand for our breast cancer test may also be impacted by other factors, including the economic environment and continued high unemployment levels, seasonal effects relating to physician and patient vacation schedules, our shift in commercial focus to our Onco*type* DX colon cancer test or any future products we may develop, and the number of clinical trials in process by cooperative groups or makers of other tests conducting experience studies.

Most national and regional third-party payors in the United States, along with the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, have issued positive coverage determinations for our Onco*type* DX breast cancer test for patients with node negative, or N-, estrogen receptor positive, or ER+, disease through contracts, agreements or policy decisions. In June 2009, the local carrier with jurisdiction for claims submitted by us for Medicare patients extended its coverage for our breast cancer test to include ER+ patients with node positive, or N+, disease (up to three positive lymph nodes). Additionally, some payors provide policy coverage for the use of our test in ER+ patients with N+ disease, including lymph node micro-metastasis (greater than 0.2 mm, but not greater than 2.0 mm in size). However, we may not be able to obtain reimbursement coverage from other payors for our test for breast cancer patients with N+, ER+ disease.

As of December 31, 2010, we had exclusive distribution agreements for our Onco*type* DX breast cancer test with distributors in 13 countries outside of the United States, and have established reimbursement arrangements for this test with several public and private payors and hospitals. We have obtained coverage for our test in Canada, Ireland, Germany, Greece, Israel and the United Kingdom and have completed or initiated multiple international studies intended to support the adoption of our breast cancer test outside of the United States. In October 2010, we announced positive results from our first European clinical decision impact study demonstrating that knowledge of the Onco*type* DX breast cancer Recurrence Score result changed oncologist s treatment decisions in over 30% of patients, which is consistent with U.S. decision impact studies. In November 2010, *Breast Cancer Research Treatment* published positive results from a Japanese economic evaluation study demonstrating that the inclusion of Onco*type* DX in Japan s social health insurance benefit package would be cost effective. In December 2010, we presented positive preliminary results from a large adjuvant breast cancer trial with clinical researchers in Germany using the Onco*type* DX breast cancer test to select patients for study randomization and treatment.

Oncotype DX Colon Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Onco*type* DX colon cancer test, which we launched in January 2010. We believe the key factors that will drive adoption of this test include publication of peer-reviewed articles on the QUASAR clinical validation study and other studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia and our ongoing commercial efforts. We are working with public and private payors and health plans to secure coverage for our colon cancer test based upon clinical evidence showing the utility of the

test. We may need to hire additional commercial, scientific, technical and other personnel to support this process.

We have obtained limited reimbursement coverage from third-party payors for our Onco*type* DX colon cancer test. As a new test, our colon cancer test may be considered investigational by payors and therefore may not be covered under their reimbursement policies. Consequently, we intend to pursue case-by-case reimbursement and

expect that this test will continue to be reviewed on this basis until policy decisions have been made by individual payors. We are also working with public and private payors and health plans to secure coverage for our Onco*type* DX colon cancer test based upon clinical evidence showing the utility of the test. We believe it may take several years to achieve reimbursement with a majority of third-party payors for our colon cancer test. However, we cannot predict whether, or under what circumstances, payors will reimburse for this test. Based upon our experience in obtaining adoption of and reimbursement for our Onco*type* DX breast cancer test, we do not expect product revenues from our colon cancer test to comprise more than 10% of our total revenues for at least the next year or more.

During the second quarter of 2010, we completed sample processing for our second stage II colon cancer recurrence study and plan to report results in 2011. We also initiated the first treatment decision impact study of our colon cancer test and are currently enrolling patients. We are planning additional studies to support the clinical utility and assess the treatment impact and health economic benefit of our colon cancer test.

Product Pipeline

We are investigating the utility of Onco*type* DX in patients with ductal carcinoma in situ, or DCIS, breast cancer, which generally refers to a pre-invasive tumor with reduced risk of recurrence. In early 2010, we presented positive results from a DCIS breast cancer feasibility study demonstrating that ribonucleic acid, or RNA, extraction and reverse transcription polymerase chain reaction, or RT-PCR, technology can be successfully performed to assess gene expression profiles from fixed paraffin-embedded, or FPE, tissues. We plan to evaluate the use of the Onco*type* DX 21-gene breast cancer panel and also seek to identify other genes that may be used for treatment planning in DCIS. We are conducting a DCIS clinical validation study and plan to report results in the first half of 2011.

In June 2010, we presented positive results from an evaluation of biological similarities and differences between stage II and stage III colon cancer suggesting the Onco*type* DX colon cancer Recurrence Score result may also predict recurrence risk in stage III colon cancer. We plan to continue conducting early development tests to evaluate our Onco*type* DX colon cancer test for treatment planning in stage III disease, and we are also conducting studies to investigate our colon cancer test s ability to predict chemotherapy benefit in stage II and stage III colon cancer patients treated with oxaliplatin.

In December 2010, we presented positive first results from our prostate gene identification study. The study, which applied the same RT-PCR technology used in our Onco*type* DX breast and colon cancer tests, identified 295 genes strongly associated with clinical recurrence of prostate cancer following radical prostatectomy. Based on these results, we announced that we are moving forward with full clinical development for a prostate cancer test and plan to conduct multiple additional studies. We expect to report full gene identification results in 2011.

In June 2010, we presented results from our first renal gene identification study under our collaboration agreement with Pfizer Inc. 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 study results demonstrated a strong correlation between gene expression and recurrence risk in this patient population. We plan to initiate a renal cancer clinical validation study in 2011.

Technology

We are developing high-throughput, next generation sequencing, or NGS, to be our primary technology for future gene discovery. NGS technologies parallelize the sequencing process, producing thousands or millions of sequences at once. These technologies are intended to provide DNA sequence information at lower cost than standard methods. We have created proprietary methods for NGS of FPE tissue nucleic acids, created bioinformatics programs and infrastructure for data storage and analysis, and plan to rely on NGS as the basic source of new biomarkers in the

future.

Table of Contents

Economic Environment

Continuing concerns over prolonged high unemployment levels across the United States, the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget proposals, inflation, deflation, taxation issues, energy costs and geopolitical issues have contributed to increased volatility and diminished expectations for the U.S. economy. These factors, combined with declines in business and consumer confidence and a volatile stock market, have precipitated an economic slowdown and expectations of slower global economic growth going forward. We periodically evaluate 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 third-party payors in the foreseeable future. The economic environment continued to have a negative impact on growth in tests delivered during the year ended December 31, 2010, particularly in areas of the United States with high unemployment levels where patients have lost healthcare coverage, delayed medical checkups or are unable to pay for our tests. We intend to continue to assess the impact of the economic environment on our business activities. If the economic environment does not improve or deteriorates, the volume of tests delivered could continue to be negatively impacted and we could, in turn, experience lower revenues.

U.S. Healthcare Legislation

The recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or, collectively, the PPACA, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. The PPACA contains a number of provisions designed to generate the revenues necessary to fund expanded health insurance coverage, including new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, each medical device manufacturer will have to pay sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. Though there are some exceptions to the tax, because the FDA maintains that clinical laboratory tests that are developed and validated by a laboratory for its own use, or LDTs, such as our Onco*type* DX breast and colon cancer tests, are medical devices, it may apply to some or all of our current products and products in development. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, in addition to a productivity adjustment to the Clinical Laboratory Fee Schedule. In addition, the PPACA establishes a board that is charged with reducing the per capita rate of growth in Medicare spending. These reductions in payments may apply to some or all of our clinical laboratory tests delivered to Medicare beneficiaries.

We are monitoring the impact of the PPACA in order to enable us to determine the trends and changes that may be necessitated by the legislation that may potentially impact on our business over time.

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 and liabilities 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.

Table of Contents

Revenue Recognition

We determine 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 on an accrual basis when the following 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. 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.

As of December 31, 2010, we had distributor agreements in 13 countries outside of the United States The distributor provides us with certain marketing and administrative services within its territory. As a condition of these agreements, the distributor pays us an agreed upon fee per test and we process the tests. The same revenue recognition criteria described above generally apply to tests received through international distributors. Product revenues for tests performed are recognized on an accrual basis 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. To the extent all criteria set forth above are not met when test results are delivered, product revenues are generally recognized when cash is received from the distributor.

Test revenue recognized on an accrual basis is recorded upon delivery of each test performed, net of any contractual discount at the amount that we expect to collect. We determine the amount we expect to collect on a per payor, per contract or agreement basis, based on our analysis of historical average payments. This average amount is typically lower than the agreed upon amount due to several factors, such as the amount of patient co-payments, the existence of secondary payors and claim denials. We typically review our analysis annually, or at the time a contractual price change is implemented or when information comes to our attention that leads us to believe an adjustment may be warranted.

As of December 31, 2010, amounts outstanding for tests delivered, net of write-downs and adjustments, which were not recognized as revenue upon delivery because our accrual revenue recognition criteria were not met and which had not been collected, totaled approximately $33 million. We cannot provide any assurance as to when, if ever, and to what extent these amounts will be collected.

From time to time, we receive requests for refunds of payments, generally due to overpayments made by third-party payors. Upon becoming aware of a refund request, we establish an accrued liability for tests covered by the refund request until such time as we determine whether or not a refund is due. If we determine that a refund is due, we credit cash and reduce the accrued liability. Accrued refunds were $659,000 and $757,000 at December 31, 2010 and 2009, respectively.

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 and 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.

Accounts Receivable

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

Table of Contents

trends or significant events indicate that a change in estimate is appropriate. Historically, the amounts of uncollectible accounts receivable that have been written off have been consistent with management s expectations. We cannot assure you that we will not experience higher than expected write-offs in the future. As of December 31, 2010 and 2009, our allowance for doubtful accounts was $680,000 and $545,000, respectively. See Liquidity and Capital Resources for additional information, including a summary of accounts receivable aging by payor mix.

Research and Development Expenses

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. The financial terms of these agreements are subject to negotiations, may vary from contract to contract, and may result in uneven payment flows. We determine our estimates through discussion with internal clinical development personnel and outside service providers as to the progress or stage of completion of services provided and the agreed upon fee to be paid for such services. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

All potential future product programs outside of breast and colon cancer are in the research or early development phase. Although we have estimated the time frame in which some of these products may be brought to market, the timing is uncertain given the technical challenges and clinical variables that exist between different types of cancers. We maintain 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

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 valuation model and is recognized as expense ratably over the requisite service period. The application of option valuation models requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Black-Scholes option valuation model 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. Our assumptions regarding expected volatility are based on the historical volatility of our common stock. 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.

We review our valuation assumptions on an ongoing basis, and, as a result, our assumptions used to value employee stock-based awards granted in future periods may change. See Note 9, 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.

Deferred Tax Assets

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential

effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, we determined that, based on all available evidence, there was substantial uncertainty as to our ability to realize recorded net deferred taxes in future

Table of Contents

periods. Accordingly, we recorded a valuation allowance against all of our net deferred tax assets for the years ended December 31, 2010 and 2009, respectively.

Results of Operations

Comparison of Years Ended December 31, 2010, 2009 and 2008

We recorded net income of $4.3 million for the year ended December 31, 2010, compared to a net loss for the years ended December 31, 2009 and 2008 of $9.4 million and $16.1 million, respectively. On a basic per share basis, net income was $0.15 for the year ended December 31, 2010 and net loss was $0.33 and $0.57 for the years ended December 31, 2009 and 2008, respectively. On a diluted per share basis, net income was $0.14 for the year ended December 31, 2010 and net loss was $0.33 and $0.57 for the years ended December 31, 2009 and 2008, respectively. We may incur net losses in future periods due to future spending and fluctuations in our business, and we may not maintain profit levels in the future.

Revenues

We derive our revenues primarily from product sales and, to a lesser extent, from contract research arrangements. We operate in one industry segment. As of December 31, 2010, substantially all of our product revenues have been derived from the sale of our Onco*type* DX breast cancer 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 arrangement to pay 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,		
	2010	2009	2008
	(In thousands)		
Product revenues	$ 174,870	$ 146,581	$ 108,658
Contract revenues	3,231	2,967	1,921
Total revenues	$ 178,101	$ 149,548	$ 110,579
Year over year dollar increase in product revenues	$ 28,289	$ 37,923	
Year over year percentage increase in product revenues	19%	35%	

The year over year increases in product revenues resulted from increased adoption, as evidenced by a 17% increase in test volume for the year ended December 31, 2010 and a 24% increase in test volume for the year ended December 31, 2009. We also experienced expanded reimbursement coverage and an increase in revenues recorded on an accrual basis. Approximately $97.7 million, or 56%, of product revenues for the year ended December 31, 2010, were recorded on an accrual basis and recognized at the time the test results were delivered, compared to $75.3 million, or 51%, and $55.1 million, or 51%, of product revenues for the years ended December 31, 2009 and 2008, respectively. For all periods, the balance of product revenues was recognized upon cash collection as payments were received.

Product revenues related to Medicare patients for the year ended December 31, 2010 were $36.3 million, or 21%, of product revenues, compared to $28.8 million, or 20%, and $23.7 million, or 22%, of product revenues for the years ended December 31, 2009 and 2008, respectively. There were no other third-party payors comprising product

revenues of 10% or more for those years. International product revenues were $10.1 million, or 6% of product revenues, for the year ended December 31, 2010, compared to $6.1 million, or 4% of product revenues, and $3.7 million, or 3% of product revenues, for the years ended December 31, 2009 and 2008, respectively.

Product revenues for the year ended December 31, 2009 were affected by delayed receipt of approximately $2.5 million in payments from two third-party payors. The delays resulted from interruptions in payments due to contract and documentation requirements, which were resolved and recorded in the first half of 2010. The timing of recognition of revenue related to these and other third-party payments may cause fluctuations in product revenues from period to period.

Table of Contents

Contract revenues were $3.2 million, $3.0 million and $1.9 million for the years ended December 31, 2010, 2009 and 2008, 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 2010 compared to 2009 was due primarily to the recognition of deferred revenue from a previously completed contract. The increase in contract revenues for 2009 compared to 2008 was due entirely to ongoing activities related to our collaboration with Pfizer Inc. We expect that our contract revenues will continue to fluctuate based on the number and timing of studies being conducted.

Cost of Product Revenues

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Tissue sample processing costs	$ 23,802	$ 22,103	$ 18,893
Employee stock-based compensation	342	364	491
Total tissue sample processing costs	24,144	22,467	19,384
License fees	10,490	10,095	7,801
Total cost of product revenues	$ 34,634	$ 32,562	$ 27,185
Year over year dollar increase	$ 2,072	$ 5,377	
Year over year percentage increase	6%	20%	

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, 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 tests are recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. While license fees are generally calculated as a percentage of product revenues, the percentage increase in license fees does not correlate exactly to the percentage increase in product revenues because certain agreements contain provisions for fixed annual payments and other agreements have tiered rates and payments that may be capped at annual minimum or maximum amounts. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

Tissue sample processing costs increased $1.7 million, or 8%, in 2010 compared to 2009, and $3.2 million, or 17%, in 2009 compared to 2008, driven by increases in test volume of 17% and 24% in 2010 and 2009, respectively, which were partially offset by cost controls and efficiency gains. License fees increased $395,000, or 4%, in 2010 compared to 2009 and $2.3 million, or 29%, in 2009 compared to 2008. License fees for the year ended December 31, 2010 included a decrease of approximately $1.7 million related to the discontinuance of certain license fees, representing 1% of product revenues, resulting from the abandonment of a patent by the licensor. These decreases were offset by increases in license fees (related to other licenses) of $1.8 million, due to primarily to increased product revenues, and $350,000 of expense related to fixed annual payments to one of our collaborators triggered by the January 2010

launch of our Onco*type* DX colon cancer test. We expect the cost of product revenues to increase in future periods to the extent we process more tests.

Table of Contents

Research and Development Expenses

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Personnel-related expenses	$ 16,650	$ 18,413	$ 16,534
Employee stock-based compensation	2,881	3,098	2,913
Collaboration expenses	2,244	2,192	1,433
Reagents and laboratory supplies	2,068	2,976	1,972
Infrastructure and all other costs	9,382	9,012	5,772
Total research and development expenses	$ 33,225	$ 35,691	$ 28,624
Year over year dollar increase (decrease)	$ (2,466)	$ 7,067	
Year over year percentage increase (decrease)	(7)%	25%	

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 $2.5 million, or 7%, decrease in research and development expenses for 2010 compared to 2009 included a $1.8 million decrease in personnel-related expenses and a $908,000 decrease in reagents and laboratory supplies expense due primarily to cost controls, efficiency gains, project timing and reagents and supplies use for ongoing research and development activities, and the movement of our Onco*type* DX colon cancer test from development and commercialization in 2009 to product launch in 2010. These decreases were partially offset by a $370,000 increase in infrastructure and other expenses, including allocated information technology salaries and benefits and other costs for projects related to NGS. Of the $1.8 million decrease in personnel-related expenses, $1.0 million was attributable to decreases in salaries, benefits and related expenses, $431,000 was related to lower bonus payments and $298,000 was attributable to decreased contract labor and consulting expenses. The decreases in salaries and bonus payments were primarily due to lower headcount, as open positions resulting from attrition had not been filled in 2010.

The $7.1 million, or 25%, increase in research and development expenses for 2009 compared to 2008 included a $2.5 million increase in allocated information technology salaries and benefits and other costs related to the development of our colon cancer test, a $1.9 million increase in personnel-related expenses, a $1.0 million increase in reagents and laboratory supplies, a $759,000 increase in collaborations expense due primarily to gene discovery work and a $740,000 increase in infrastructure and other costs. The $1.9 million increase in personnel-related expenses included $1.6 million in salary increases and $266,000 in higher benefits and other expenses. The increases in reagents, laboratory supplies and collaboration expenses were primarily due to early development studies for renal, prostate, and small-cell lung cancer programs. We expect our research and development expenses due to increased investment in new our product pipeline for breast, colon, renal, prostate and other cancers.

Table of Contents

Selling and Marketing Expenses

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Personnel-related expenses	$ 35,288	$ 29,589	$ 21,208
Employee stock-based compensation	3,086	3,171	2,622
Promotional and marketing materials	13,665	12,402	10,961
Travel, meetings and seminars	8,253	7,468	6,086
Infrastructure and all other costs	11,113	8,502	5,791
Total selling and marketing expenses	$ 71,405	$ 61,132	$ 46,668
Year over year dollar increase	$ 10,273	$ 14,464	
Year over year percentage increase	17%	31%	

Our selling and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses and infrastructure expenses, including allocated facility occupancy and information technology costs. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding our genomic technologies, how our Onco*type* DX tests are developed and validated and the value of the quantitative information that our tests provide. Selling and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and economic publications related to our Onco*type* DX tests. Our sales force compensation includes annual salaries and eligibility for quarterly commissions based on the achievement of predetermined sales goals.

The $10.3 million, or 17%, increase in selling and marketing expenses for 2010 compared to 2009 was primarily due to a $5.7 million increase in personnel-related expenses, a $2.6 million increase in infrastructure and other expenses, including allocations for information technology, recruiting and other expenses, a $1.3 million increase in promotional field expenses and marketing materials and a $785,000 increase in travel, meetings and seminars expenses. These increases included costs related to the addition of eight U.S. sales representatives in January 2010 and to our continued international expansion efforts. Of the $5.7 million increase in personnel-related expenses, $2.8 million was attributable to increases in salaries, benefits and related expenses, $1.7 million was attributable to higher consulting expenses to support our international expansion and colon cancer product launch and $1.2 million was attributable to higher commissions and bonus payments.

The $14.5 million, or 31%, increase in selling and marketing expenses for 2009 compared to 2008 was primarily due to an $8.4 million increase in personnel-related expenses, a $2.7 million increase in infrastructure and other expenses, a $1.5 million increase in promotional field expenses and marketing materials, a $1.4 million increase in travel-related expenses, and a $549,000 increase in stock-based compensation. These increases included costs related to the addition of 20 U.S. sales representatives in January 2009 and to our international expansion activities. Of the $8.4 million increase in personnel-related expenses, $6.3 million was attributable to increases in salaries, benefits and related expenses, $1.0 million was attributable to higher consulting expenses to support our international expansion and colon product launch, $866,000 was attributable to higher commissions and bonus payments, and $213,000 was attributable to increases in recruiting and relocation expenses.

We expect selling and marketing expenses will continue to increase in future periods due to our efforts to establish adoption of and reimbursement for our Onco*type* DX colon cancer test, continued investment in our global

commercial infrastructure and increases in our sales force.

Table of Contents

General and Administrative Expenses

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Personnel-related expenses	$ 13,591	$ 10,001	$ 9,184
Employee stock-based compensation	4,035	3,522	3,112
Billing and collection fees	6,524	5,611	3,922
Bad debt expense	2,231	1,438	1,278
Professional fees and all other costs	8,532	8,992	8,121
Total general and administrative expenses	$ 34,913	$ 29,564	$ 25,617
Year over year dollar increase	$ 5,349	$ 3,947	
Year over year percentage increase	18%	15%	

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

The $5.3 million, or 18%, increase in general and administrative expenses for 2010 compared to 2009 included a $3.6 million increase in personnel-related expenses, including the addition of in-house legal staff in 2010 and in the second half of 2009, salary increases and benefits expenses, a $913,000 increase in billing and collection fees related to increased test volume and cash collections, a $793,000 increase in bad debt expense and a $513,000 increase in stock-based compensation, partially offset by a $326,000 decrease in professional fees, including legal expenses.

The $3.9 million, or 15%, increase in general and administrative expenses for 2009 compared to 2008 included a $1.7 million increase in billing and collection fees related to increases in the number of tests processed and cash collections, an $817,000 increase in personnel-related expenses, including the addition of in-house legal staff in the second half of 2009, salary increases and benefits expenses, a $547,000 increase in professional fees, due primarily to legal fees for regulatory and international matters, a $410,000 increase in stock-based compensation, a $213,000 increase in infrastructure expenses, a $176,000 increase in travel-related expenses and a $161,000 increase in bad debt expense.

We expect general and administrative expenses to increase in future periods as we hire additional staff and incur other expenses to support the growth of our business, and to the extent we spend more on both billing and collections fees and bad debt expense. We expect billing and collections fees and bad debt expense in total will continue to be approximately 5% of product revenues for at least the next year or more.

Interest and Other Income

Interest and other income was $277,000 for the year ended December 31, 2010 compared to $670,000 and $1.8 million for the years ended December 31, 2009 and 2008, respectively. The decreases in interest and other income for 2010 and 2009 compared to the prior year comparative periods reflected lower market yields on our investment portfolio. We expect our interest income will remain nominal if the current low interest rate environment continues.

Interest and Other Expense

Interest and other expense was $49,000 for the year ended December 31, 2010 compared to $120,000 and $386,000 for the years ended December 31, 2009 and 2008, respectively. The decreases in interest and other expense for 2010 and 2009 compared to prior year comparative periods were primarily due to lower average balances on our equipment financing notes as we paid them down. These notes were paid in full as of November 2010. We do not anticipate using additional equipment financing as a funding source in the next twelve months.

Table of Contents

Income Tax Expense (Benefit)

For the year ended December 31, 2010, we recorded an income tax benefit of $136,000, which was principally comprised of a benefit for the reversal of 2009 alternative minimum income tax, partially offset by other state income taxes and foreign taxes. For the year ended December 31, 2009, we recorded income tax expense of approximately $560,000, which was principally comprised of California state income tax, federal alternative minimum tax and foreign income taxes. For the year ended December 31, 2008, we recorded income tax benefit of approximately $61,000, which was comprised of minimum state income taxes excluding the impact of an estimated refundable credit receivable.

As a result of historical losses since inception and based on all available evidence, we continue to believe that there is substantial uncertainty as to whether we will recover recorded net deferred taxes in future periods. Accordingly, we continue to maintain a full valuation allowance on our net deferred tax assets for the years ended December 31, 2010 and 2009, respectively. We intend to maintain a full valuation allowance on our deferred tax assets until sufficient evidence exists to support the reversal of all or some portion of these allowances.

Liquidity and Capital Resources

As of December 31, 2010, we had an accumulated deficit of $173.6 million. We may incur net losses in the future, and we cannot provide assurance as to when, if ever, we will achieve sustained profitability. We expect that our research and development, selling and marketing and general and administrative expenses will increase in future periods and, as a result, we will need to continue to generate significant product revenues to achieve sustained profitability.

Sources of Liquidity

At December 31, 2010, we had cash, cash equivalents and short-term investments of $76.8 million compared to $57.4 million at December 31, 2009. The $19.4 million increase was attributable to increased cash collections from sales of our tests, payments from collaborators and cash received from the exercise of employee stock options, which were partially offset by investments in the growth of our business, including research and development, international expansion and activities related to our colon cancer product launch in January 2010. 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, U.S. Treasury securities, debt obligations of U.S. government-sponsored entities, and high-grade commercial paper and corporate bonds.

Historically we have financed our operations primarily through sales of our equity securities and cash received in payment for our tests. Purchases of equipment and leasehold improvements have been partially financed through capital equipment financing arrangements. Our notes payable under these arrangements were paid in full as of November 2010.

Accounts Receivable

At December 31, 2010 and 2009, $14.3 million, or 13%, and $11.1 million, or 13%, respectively, of our total assets consisted of accounts receivable. The $3.2 million year over year increase in accounts receivable was attributable to additional payors moving from cash basis to accrual basis during 2010. Days sales outstanding, or DSOs, is a measure of the average number of days it takes for us to collect our accounts receivable, calculated from the date that tests are billed. At December 31, 2010 and 2009, our average DSOs were 52 days and 48 days, respectively. The timing of our billing and cash collections causes fluctuations in our monthly DSOs and accounts receivable.

61

Table of Contents

The following tables summarize accounts receivable by payor mix at December 31, 2010 and 2009:

	December 31, 2010							
	Total	% of Total	Current	31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
				(In thousands)				
Managed care and other	$ 9,725	65%	$ 5,367	$ 1,598	$ 706	$ 525	$ 579	$ 950
Medicare	5,261	35	4,070	666	73	110	103	239
Total	14,986	100%	$ 9,437	$ 2,264	$ 779	$ 635	$ 682	$ 1,189
Allowance for doubtful accounts	(680)							
Net accounts receivable	$ 14,306							

	December 31, 2009							
	Total	% of Total	Current	31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
				(In thousands)				
Managed care and other	$ 6,591	56%	$ 3,391	$ 1,164	$ 563	$ 386	$ 410	$ 677
Medicare	5,077	44	1,459	2,018	885	218	193	304
Total	11,668	100%	$ 4,850	$ 3,182	$ 1,448	$ 604	$ 603	$ 981
Allowance for doubtful accounts	(545)							
Net accounts receivable	$ 11,123							

Cash Flows

	2010	2009	2008
		(In thousands)	
As of December 31:			
Cash, cash equivalents and short-term investments	$ 76,818	$ 57,448	$ 56,670
Working capital	76,097	55,541	52,693
For the year ended December 31:			
Cash provided by (used in):			

Operating activities	21,583	4,826	(818)
Investing activities	(2,240)	(6,837)	(26,167)
Financing activities	2,758	(78)	(1,008)
Capital expenditures (included in investing activities above)	(4,442)	(3,744)	(10,057)

Net cash provided by operating activities for the year ended December 31, 2010 was $21.6 million, compared to net cash provided by operating activities of $4.8 million and net cash used in operating activities of $818,000 for the years ended December 31, 2009 and 2008, respectively. Net cash provided by (used in) operating activities includes net income (loss) adjusted for certain non-cash items and changes in assets and liabilities. Net cash provided by operating activities of $21.6 million for the year ended December 31, 2010 reflected net income of $4.2 million, adjusted for $17.5 million of depreciation and stock-based compensation expense, a $2.7 million increase in accounts payable and a $1.2 million increase in accrued compensation expense, partially offset by a $3.2 million increase in accounts receivable and a $2.4 million increase in prepaid expenses and other assets. Net cash provided by operating activities of $4.8 million for the year ended December 31, 2009 reflected a net loss of $9.4 million, adjusted for $16.7 million of depreciation and stock-based compensation expense, and a $2.0 million increase in accrued compensation expense, partially offset by a $3.4 million increase in accounts receivable, prepaid assets and other assets and a $1.6 million decrease in deferred revenues. Net cash used in operating activities of $818,000 for the year ended December 31, 2008 reflected a net loss of $16.1 million, adjusted for $14.1 million of depreciation and stock-based compensation expense, and a $5.4 million increase in accounts receivable, prepaid assets and other assets, partially offset by a $3.2 million increase in accrued expenses and other liabilities, a

Table of Contents

$2.8 million increase in deferred revenue, which included $3.7 million in advance collaboration contract payments, and a $485,000 increase in accrued compensation expense.

Net cash used in investing activities was $2.2 million for the year ended December 31, 2010, compared to net cash used in investing activities of $6.8 million and $26.2 million for the years ended December 31, 2009 and 2008, respectively. Our investing activities have consisted predominantly of purchases and maturities of marketable securities and capital expenditures. Net cash used in investing activities of $2.2 million for the year ended December 31, 2010 included $4.4 million of capital expenditures and a $500,000 investment in non-marketable equity securities, partially offset by $2.7 million in net maturities of marketable securities. Net cash used in investing activities of $6.8 million for the year ended December 31, 2009 included $3.1 million in net purchases of marketable securities and $3.7 million of capital expenditures. Net cash used in investing activities of $26.2 million for the year ended December 31, 2008 included $16.1 million in net purchases of marketable securities as we invested a portion of the cash proceeds from our May 2007 public offering of common stock and $10.1 million of capital expenditures for facility expansion and improvements.

Net cash provided by financing activities was $2.8 million for the year ended December 31, 2010, compared to net cash used in financing activities of $78,000 and $1.0 million for the years ended December 31, 2009 and 2008, respectively. Our financing activities included sales of our equity securities and capital equipment financing arrangements. Net cash provided by financing activities of $2.8 million for the year ended December 31, 2010 included $3.0 million in proceeds from issuance of common stock, partially offset by $225,000 in payments on our equipment financing notes payable, which were paid in full in November 2010. Net cash used in financing activities of $78,000 for the year ended December 31, 2009 included $1.8 million in payments on our notes payable, partially offset by $1.7 million in proceeds from issuance of common stock. Net cash used in financing activities of $1.0 million for the year ended December 31, 2008 included $2.7 million in payments on our notes payable, partially offset by $1.7 million in proceeds from issuance of common stock.

Contractual Obligations

The following table summarizes our significant contractual obligations as of December 31, 2010 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)		
Non-cancelable operating lease obligations	$ 21,208	$ 2,443	$ 5,707	$ 6,028	$ 7,030

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 November 2010, we exercised an option to extend the term of this lease to March 2019. In January 2007, we entered into a non-cancelable lease for 48,000 square feet of additional laboratory and office space in a nearby location. In November 2010, we exercised an option to extend the term of this lease to March 2018. In October 2009, we entered into a non-cancelable lease an additional 30,500 square feet of office space in a nearby location. This lease expires in March 2018. In May 2010, we entered into a non-cancelable lease for 2,500 square feet of property in Geneva, Switzerland. This lease expires in May 2015.

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 our Onco*type* DX breast cancer test. We made payments under this agreement of $475,000 in each of the years 2007, 2008, 2009 and 2010. A final annual payment of $475,000 was made under this agreement in January 2011. We are also required to make a series of fixed annual payments under a separate collaboration agreement beginning with the January 2010 launch of our Onco*type* DX colon cancer test. We made a payment of $150,000 in 2010. As of December 31, 2010, future annual payments under this agreement totaled $1.9 million, of which $200,000 is due in 2011, $300,000 is due in 2012 and $450,000 is due in each of the years 2013, 2014 and 2015. However, because both of these agreements may be terminated by either party upon 30 days prior written notice, these payments are not included in the table above.

Table of Contents

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, 2010, we had no material off-balance sheet arrangements.

Operating Capital and Capital Expenditure Requirements

We achieved positive operating cash flow for the years ended December 31, 2010 and 2009. We currently anticipate that our cash, cash equivalents and short-term investments, together with payments for our Onco*type* DX tests, will be sufficient to fund our operations and facilities expansion plans for at least the next 12 months, including the expansion of our research and development programs, establishment of adoption of and reimbursement for our Onco*type* DX colon cancer test, and our international expansion efforts. We expect to spend approximately $8.0 million over the next 12 months for planned laboratory equipment, information technology expansion and facilities expansion. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We expect that our cash, cash equivalents and short term investments will be also be used to fund working capital and for other general corporate purposes, such as licensing technology rights, distribution arrangements for our tests outside of the United States or expanding our direct sales capabilities outside of the U.S.

The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the amount of cash provided by our operations, the progress of our commercialization efforts, product development, regulatory requirements, progress in reimbursement for our tests and available strategic opportunities for acquisition of or investment in complementary businesses, technologies, services or products.

We cannot be certain that our international expansion plans, efforts to establish adoption of and reimbursement for our Onco*type* DX colon cancer test or the development of future products will be successful or that we will be able to raise sufficient additional funds to see these activities through to a successful result. It may take years to move any one of a number of product candidates in research through development and validation to commercialization.

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

- the rate of progress in establishing reimbursement arrangements with domestic and international 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 our Onco*type* DX breast and colon cancer tests;
- the rate of progress and cost of selling and marketing activities associated with establishing adoption of and reimbursement for our Onco*type* DX colon cancer test;
- the rate of progress and cost of research and development activities associated with products in research and early development focused on cancers other than breast and colon cancer;
- costs related to future product launches;

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;

Table of Contents

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

the impact of changes in Federal, state and international taxation; and

the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter or investments or acquisitions we might seek to effect.

If we are not able to generate and maintain sustained product revenues to finance our cash requirements, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also 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. The terms of debt securities or borrowings 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 market and financial services industry have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. If we are not able to secure additional funding when needed, on acceptable terms, 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 could lower the economic value of those programs to us.

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board, or FASB, issued authoritative guidance for applying the milestone method of revenue recognition to research and development arrangements. Under this guidance, revenue contingent upon the achievement of a milestone in its entirety may be recognized in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. This guidance is effective on a prospective basis for research and development milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. This guidance, which we do not expect to have a material impact on our financial condition and results of operations, will become effective for us on January 1, 2011.

In October 2009, the FASB issued authoritative guidance that amends existing guidance for identifying separate deliverables in a revenue-generating transaction where multiple deliverables exist, and provides guidance for allocating and recognizing revenue based on those separate deliverables. The guidance is expected to result in more multiple-deliverable arrangements being separable than under current guidance and is required to be applied prospectively to new or significantly modified revenue arrangements. This guidance, which we do not expect to have a material impact on our financial condition and results of operations, will become effective for us on January 1, 2011.

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

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to interest earned on 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, commercial paper and corporate bonds, are subject to default, changes in credit rating and changes in market value. These investments are subject to interest rate risk and will decrease in value if market interest rates increase.

Our cash, cash equivalents and marketable securities, totaling $76.8 million at December 31, 2010, did not include any auction preferred stock, auction rate securities or mortgage-backed investments. We currently do not

Table of Contents

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, 2010, the impact on the fair value of these securities or our cash flows or income would not be material.

Foreign Currency Exchange Risk

Substantially all of our revenues are recognized in U.S. dollars. Certain expenses related to our international activities are payable in foreign currencies. As a result, factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets will affect our financial results. We recognized net realized foreign exchange transaction losses of $35,000 for the year ended December 31, 2010. We had no foreign currency transaction gains or losses for the years ended December 31, 2009 and 2008, respectively, as our total payables denominated in foreign currency during those periods were not material. The functional currency of our wholly-owned European subsidiary is the U.S. dollar, so we are not currently subject to gains and losses from foreign currency translation of the subsidiary financial statements. We currently do not hedge foreign currency exchange rate exposure. Although the impact of currency fluctuations on our financial results has been immaterial in the past, there can be no guarantee the impact of currency fluctuations related to our international activities will not be material in the future.

Table of Contents

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

Genomic Health, Inc.

Index to consolidated financial statements

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Genomic Health, Inc.

We have audited the accompanying consolidated balance sheets of Genomic Health, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2010. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and schedule 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genomic Health, Inc. at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, 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), Genomic Health, Inc. s internal control over financial reporting as of December 31, 2010, 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 11, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 11, 2011

Table of Contents

GENOMIC HEALTH, INC.

Consolidated Balance Sheets

	December 31,	
	2010	2009
	(In thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,183	$ 9,082
Short-term investments	45,635	48,366
Accounts receivable (net of allowance for doubtful accounts; 2010 $680, 2009 $545)	14,306	11,123
Prepaid expenses and other current assets	6,541	5,677
Total current assets	97,665	74,248
Property and equipment, net	10,345	12,865
Restricted cash	608	500
Other assets	2,243	494
Total assets	$ 110,861	$ 88,107
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,968	$ 1,304
Accrued compensation	7,352	6,188
Accrued license fees	3,126	3,016
Accrued expenses and other current liabilities	5,584	5,372
Notes payable		225
Deferred revenues current portion	1,295	2,238
Other current liabilities	243	364
Total current liabilities	21,568	18,707
Deferred revenues long-term portion	1,526	
Other liabilities	1,657	891
Commitments (Note 8)		
Stockholders equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2010 and 2009		
Common stock, $0.0001 par value; 100,000,000 shares authorized, 29,007,564 and 28,681,047 shares issued and outstanding at December 31, 2010 and 2009 respectively	3	2
Additional paid-in capital	259,724	246,383
Accumulated other comprehensive income (loss)	(10)	19

Accumulated deficit	(173,607)	(177,895)
Total stockholders equity	86,110	68,509
Total liabilities and stockholders equity	$ 110,861	$ 88,107

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

Consolidated Statements of Operations

	Year Ended December 31,		
	2010	2009	2008
	(In thousands, except per share amounts)		
Revenues:			
Product revenues	$ 174,870	$ 146,581	$ 108,658
Contract revenues	3,231	2,967	1,921
Total revenues	178,101	149,548	110,579
Operating expenses:			
Cost of product revenues	34,634	32,562	27,185
Research and development	33,225	35,691	28,624
Selling and marketing	71,405	61,132	46,668
General and administrative	34,913	29,564	25,617
Total operating expenses	174,177	158,949	128,094
Income (loss) from operations	3,924	(9,401)	(17,515)
Interest and other income	277	670	1,751
Interest and other expense	49	120	386
Income (loss) before income taxes	4,152	(8,851)	(16,150)
Income tax expense (benefit)	(136)	560	(61)
Net income (loss)	$ 4,288	$ (9,411)	$ (16,089)
Basic net income (loss) per share	$ 0.15	$ (0.33)	$ (0.57)
Shares used in computing basic net income (loss) per share	28,815	28,563	28,298
Diluted net income (loss) per share	$ 0.14	$ (0.33)	$ (0.57)
Shares used in computing diluted net income (loss) per share	29,653	28,563	28,298

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

Consolidated Statements of Stockholders Equity

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders
	Shares	Amount	Capital	(Loss)	Deficit	Equity
			(In thousands)			
Balance at December 31, 2007	28,182	$ 2	$ 223,507	$ 52	$ (152,395)	$ 71,166
Issuance of common stock upon exercise of stock options for cash	279		1,679			1,679
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)
Unrealized gain on investments				193		193
Comprehensive loss						(15,896)
Balance at December 31, 2008	28,461	2	234,412	245	(168,484)	66,175
Issuance of common stock upon exercise of stock options for cash	220		1,736			1,736
Stock-based compensation expense related to employee stock options			10,155			10,155
Stock-based compensation expense related to consultant stock options			80			80
Comprehensive loss:						
Net loss					(9,411)	(9,411)
Unrealized loss on investments				(226)		(226)
Comprehensive loss						(9,637)
Balance at December 31, 2009	28,681	$ 2	$ 246,383	$ 19	(177,895)	$ 68,509
Issuance of common stock upon exercise of stock options for cash	327	1	2,982			2,983
			10,344			10,344

Stock-based compensation expense related to employee stock options						
Stock-based compensation expense related to consultant stock options			15			15
Comprehensive income:						
Net income					4,288	4,288
Unrealized loss on investments				(29)		(29)
Comprehensive income						4,259
Balance at December 31, 2010	29,008	$ 3	$ 259,724	$ (10)	$ (173,607)	$ 86,110

See accompanying notes.

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Table of Contents

GENOMIC HEALTH, INC.

Consolidated Statements of Cash Flows

	2010	December 31, 2009	2008
		(In thousands)	
Operating activities			
Net income (loss)	$ 4,288	$ (9,411)	$ (16,089)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	7,180	6,591	5,012
Employee stock-based compensation	10,344	10,155	9,138
Non-employee stock-based compensation	15	80	88
Gain on disposal of property and equipment	(45)	(44)	
Changes in assets and liabilities:			
Accounts receivable	(3,183)	(2,316)	(3,718)
Prepaid expenses and other assets	(2,365)	(1,127)	(1,687)
Accounts payable	2,664	(594)	(68)
Accrued compensation	1,164	2,031	485
Accrued expenses and other liabilities	938	1,021	3,231
Deferred revenues	583	(1,560)	2,790
Net cash provided by (used in) operating activities	21,583	4,826	(818)
Investing activities			
Purchase of property and equipment	(4,442)	(3,744)	(10,057)
Purchase of short-term investments	(84,303)	(60,318)	(112,109)
Maturities of short-term investments	87,005	57,225	95,999
Investment in equity method investee	(500)		
Net cash used in investing activities	(2,240)	(6,837)	(26,167)
Financing activities			
Principal payments of notes payable	(225)	(1,814)	(2,687)
Proceeds from issuance of common stock upon exercise of stock options	2,983	1,736	1,679
Net cash provided by (used in) financing activities	2,758	(78)	(1,008)
Net increase (decrease) in cash and cash equivalents	22,101	(2,089)	(27,993)
Cash and cash equivalents at the beginning of period	9,082	11,171	39,164
Cash and cash equivalents at the end of period	$ 31,183	$ 9,082	$ 11,171
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 13	$ 120	$ 386

Cash paid for income taxes	$ 622	$ 28	$

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2010

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a molecular diagnostics company focused on the development and global commercialization of genomic-based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. The Company was incorporated in Delaware in August 2000. The Company s first product, the Onco*type* DX breast cancer test, 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. In January 2010, the Company launched its second product, the Onco*type* DX colon cancer test, which is used to predict the likelihood of colon cancer recurrence in patients with stage II disease.

Principles of Consolidation

The consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. The Company has three wholly-owned subsidiaries. Genomic Health International LLC, a European subsidiary that was established in 2009, and Genomic Health, LLC, a Delaware limited liability company that was established in December 2010, support the Company s international sales and marketing efforts. Oncotype Laboratories, Inc., which was established in 2003, is inactive. The functional currency for Genomic Health International LLC is the U.S. dollar. All significant intercompany balances and transactions have been eliminated.

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 GAAP 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.

Cash Equivalents

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

Marketable Securities

The Company invests in marketable securities, primarily money market funds, obligations of U.S. Government agencies and government-sponsored entities, corporate bonds and commercial paper. The Company considers all investments with a maturity date of 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, 2010 and 2009, respectively, all investments in marketable securities 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 initially 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. The cost of securities sold is determined using specific identification.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Fair Value of Financial Instruments

The Company s financial instruments consist principally of cash and cash equivalents, marketable securities, trade receivables, accounts payable and notes payable. The carrying amounts of certain of these financial instruments, including cash and cash equivalents, trade receivables and accounts payable, approximate fair value due to their short maturities. Based on borrowing rates available to the Company for loans and capital lease obligations with similar terms, the carrying value of the Company s notes payable approximate fair value.

See Note 3, *Fair Value Measurements* for further information on the fair value of the Company s financial instruments

Concentration of Risk

Cash equivalents, marketable securities and trade accounts receivable are financial instruments which potentially subject the Company to concentrations of credit risk. Through December 31, 2010, no material losses had been incurred.

The Company is subject to credit risk from its portfolio of cash equivalents and marketable securities. The Company invests in money market funds 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. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company is not exposed to any significant concentrations of credit risk from these financial instruments. The goals of the Company s investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after-tax rate of return.

The Company is also subject to credit risk from its accounts receivable related to its product sales. The Company performs evaluations of customers financial condition and generally does not require collateral. The majority of the Company s accounts receivable arises from product sales in the United States and Israel. As of December 31, 2010, substantially all of the Company s product revenues have been derived from sales of one product, the Onco*type* DX breast cancer test. The majority of the Company s tests to date have been delivered to physicians in the United States. All Onco*type* DX tests are processed in the Company s clinical reference laboratory facility in Redwood City, California. One third-party payor accounted for approximately 21%, 20% and 22% of the Company s product revenues for the years ended December 31, 2010, 2009 and 2008, respectively. This payor represented 37% and 46% of the Company s net accounts receivable balance as of December 31, 2010 and 2009, respectively.

Allowance for Doubtful Accounts

The Company accrues an allowance for doubtful accounts against its accounts receivable based on estimates 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, 2010 and 2009, the Company s allowance for doubtful accounts was $680,000 and $545,000, respectively. Write-offs for doubtful accounts of $2.1 million and $1.8 million

were recorded against the allowance during the years ended December 31, 2010 and 2009, respectively. Bad debt expense was $2.2 million, $1.4 million, and $1.3 million for the years ended December 31, 2010, 2009 and 2008, respectively.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 capitalizes certain costs incurred for software developed or obtained for internal use, 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.

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. The Company s intangible assets with finite lives, which are related to patent licenses, are not material and are included in non-current other assets on the Company s consolidated balance sheets.

Equity Method Investments in Unconsolidated Affiliates

Generally, a controlling financial interest is ownership of 51% or more of the voting interest of an entity. However, a controlling financial interest may also exist in entities, such as a variable interest entity (VIE), through arrangements that do not involve controlling voting interests. The Company applies the accounting standard that requires consolidation of VIEs if the Company is the primary beneficiary, with both the power to direct the activities that most significantly impact the entity s economic performance and either the obligation to absorb losses or the right to receive benefits that could potentially be significant to the VIE.

Investments in and the operating results of 50%-or-less owned entities not required to be consolidated are included in the consolidated financial statements on the basis of the equity method of accounting. The initial investment is recorded at cost. The carrying amount of the investment is adjusted for the Company s share of earnings or losses of the investee, excluding intra-entity profits and losses, after the date of the investment. The Company s share of earnings or losses of the investee is recognized as earnings or losses in net income (loss). In December 2010, the Company invested $500,000 in the equity securities of a non-public company representing 21% of the entity s outstanding voting shares. The Company determined that is was not the primary beneficiary of this VIE and, accordingly, applied the equity method of accounting and included this investment in non-current other assets on the consolidated balance sheets as of December 31, 2010.

Impairment of Long-lived Assets

The Company reviews long-lived assets, which include property and equipment, intangible assets and equity method investments, for impairment whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. For property and equipment and intangible assets, 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. For equity method investments, evidence of impairment might include the absence of an ability to recover the carrying amount of the investment or the inability of the investee to sustain an earnings capacity which would justify the carrying amount of the investment. The Company s assessment as to whether any impairment is other than temporary is based on its ability and intent to hold the investment and whether evidence

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

indicating the carrying value of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. If the fair value of the investment is determined to be less than the carrying value and the decline in value is considered to be other than temporary, the asset is written down to its fair value. There were no impairment losses for the years ended December 31, 2010, 2009 and 2008.

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.

The Company accounts for uncertain income tax positions using a benefit recognition model with a two-step approach, a more-likely-than-not recognition criterion and a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement, in accordance with the accounting guidance for uncertain tax positions. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. Uncertain tax positions that relate only to timing of when an item is included on a tax return are considered to have met the recognition threshold. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. See Note 10, *Income Taxes*, for additional disclosures regarding unrecognized tax benefits.

Revenue Recognition

The Company derives its revenues from product sales and contract research arrangements. The Company operates in one industry segment. Substantially all of the Company s historical product revenues have been derived from the sale of the Onco*type* DX breast cancer test. The Company generally bills third-party payors 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. 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 arrangement to pay or a contract with the payor in place addressing reimbursement for the Onco*type* DX test. In the absence of such arrangements, the Company considers that criterion (1) is satisfied when a third-party payor pays the Company for the test performed. Criterion (2) is satisfied when the Company performs the test and generates and delivers to the physician, or makes available on its web portal, a Recurrence Score report. 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, 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.

As of December 31, 2010, the Company had distributor agreements in 13 countries outside of the United States. The distributor provides certain marketing and administrative services for the Company within its territory. As a condition of these agreements, the distributor pays the Company an agreed upon fee per test and the Company processes the tests. The same revenue recognition criteria described above generally apply to tests received through international distributors. Product revenues for tests performed are recognized on an accrual basis when the

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. To the extent all criteria set forth above are not met when test results are delivered, product revenues are generally recognized when cash is received from the distributor.

From time to time, the Company receives requests for refunds of payments, generally due to overpayments made by third party-payors. Upon becoming aware of a refund request, the Company establishes an accrued liability for tests covered by the refund request until such time as the Company determines whether or not a refund is due. Accrued refunds were $659,000 and $757,000 at December 31, 2010 and 2009, respectively.

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 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.

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, 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 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. Royalties for licensed technology calculated as a percentage of product revenues and fixed annual payments relating to the launch and commercialization of the Company s tests are recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations.

Research and Development Expenses

Research and development expenses are comprised of costs incurred to develop technology and carry out clinical studies and include: salaries and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services, and other outside costs. Research and development expenses also include costs related to activities performed under contracts with 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. Advance payments for goods or services

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

that will be used or rendered for future research and development activities are deferred and capitalized and recognized as expense as the goods are delivered or the related services are performed.

Stock-based Compensation

The Company uses the Black-Scholes option valuation model, which requires the use of estimates such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value employee stock-based compensation at the date of grant, and recognizes stock-based compensation expense ratably over the requisite service period.

Equity instruments granted to non-employees are valued using the Black-Scholes option valuation model and are subject to periodic revaluation over their vesting terms.

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. The Company pays dollar for dollar matching of employee contributions up to a maximum of $1,000 for each employee per year based on a full calendar year of service. The match is funded concurrently with a participant s semi-monthly contributions to the 401(k) Plan. The Company recorded expense of for its contributions under the 401(k) Plan of $431,000, $400,000 and $320,000 for the years ended December 31, 2010, 2009 and 2008 respectively.

Foreign Currency Transactions

Net foreign currency transaction gains or losses are included in interest and other expense on the Company s consolidated statements of income. Net transaction losses totaled $35,000 for the year ended December 31, 2010. We had no foreign currency transaction gains or losses for the years ended December 31, 2009 and 2008, respectively.

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 of unrealized gains and losses on available-for-sale securities.

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.

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, 2010 and 2009.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Recently Issued Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued authoritative guidance for applying the milestone method of revenue recognition to research and development arrangements. Under this guidance, revenue contingent upon the achievement of a milestone in its entirety may be recognized in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. This guidance is effective on a prospective basis for research and development milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. This guidance, which the Company does not expect to have a material impact on its financial condition and results of operations, will become effective for the Company on January 1, 2011.

In October 2009, the FASB issued authoritative guidance that amends existing guidance for identifying separate deliverables in a revenue-generating transaction where multiple deliverables exist, and provides guidance for allocating and recognizing revenue based on those separate deliverables. The guidance is expected to result in more multiple-deliverable arrangements being separable than under current guidance and is required to be applied prospectively to new or significantly modified revenue arrangements. This guidance, which the Company does not expect to have a material impact on its financial condition and results of operations, will become effective for the Company on January 1, 2011.

Note 2. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) for the period by the weighted-average number of common shares outstanding for the period without consideration of potential common shares. Diluted net income (loss) per share is calculated by dividing net income (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. The following table is a reconciliation of the numerator and denominator used in the calculation of basic and diluted net income (loss) per share:

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Numerator:			
Net income (loss)	$ 4,288	$ (9,411)	$ (16,089)
Denominator:			
Weighted-average shares of common stock outstanding used in the calculation of basic net income (loss) per share	28,815	28,563	28,298
Effect of dilutive securities: Options to purchase common stock	838		
Weighted-average shares of common stock outstanding used in the calculation of diluted net income (loss) per share	29,653	28,563	28,298
Basic net income (loss) per share	$ 0.15	$ (0.33)	$ (0.57)

Diluted net income (loss) per share	$ 0.14	$ (0.33)	$ (0.57)

Options to purchase 4.1 million weighted-average shares of the Company s common stock were outstanding during the year ended December 31, 2010, but were not included in the computation of diluted net income (loss) per share because the options exercise prices were greater than the average market price of the Company s common stock during these periods; therefore, their effect is anti-dilutive. Options to purchase 4.7 million shares of the Company s common stock were outstanding at December 31, 2009 and 2008, respectively, but are not included in the computation of diluted net income (loss) per share because their effect is anti-dilutive.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 3. Fair Value Measurements

The Company measures certain financial assets, including cash equivalents and available-for-sale securities, at their fair value on a recurring basis. The fair value of these financial assets was determined based on a hierarchy of three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

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

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

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

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 consider factors specific to the asset or liability. 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, 2010 and 2009, respectively. The following tables set forth the Company s financial instruments that were measured at fair value on a recurring basis at December 31, 2010 and 2009 by level within the fair value hierarchy:

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2010
		(In thousands)		
As of December 31, 2010:				
Assets				
Money market deposits	$ 9,956	$	$	$ 9,956
U.S. Treasury securities	3,818			3,818
Debt securities of U.S. government-sponsored agencies		20,819		20,819
Commercial paper		11,869		11,869
Corporate debt securities		9,129		9,129
Total	$ 13,774	$ 41,817	$	$ 55,591

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2009
		(In thousands)		
As of December 31, 2009:				
Assets				
Money market deposits	$ 6,011	$	$	$ 6,011
U.S. Treasury securities	4,546			4,546
Debt securities of U.S. government-sponsored agencies		44,820(1)		44,820(1)
Total	$ 10,557	$ 44,820	$	$ 55,377

(1) Includes a $1.0 million debt security maturing within three months of December 31, 2009 and classified as a cash equivalent on the consolidated balance sheets.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company s debt securities of U.S. government-sponsored entities, commercial paper and corporate bonds are classified as Level 2 as they are valued using multi-dimensional relational pricing models that use observable market inputs, including benchmark yields, reported trades, broker-dealer quotes, issuer spreads, benchmark securities, bids, offers and reference data. Not all inputs listed are available for use in the evaluation process on any given day for each security evaluation. In addition, market indicators, industry and economic events are monitored and may serve as a trigger to acquire further corroborating market data. There were no transfers between Level 1 and Level 2 categories during the years ended December 31, 2010 and 2009, respectively.

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

	December 31, 2010			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
U.S. Treasury securities	$ 3,818	$	$	$ 3,818
Debt securities of U.S. government-sponsored entities	20,825	1	(7)	20,819
Commercial paper	11,868	2	(1)	11,869
Corporate debt securities	9,134	0	(5)	9,129
Total	$ 45,645	$ 3	$ (13)	$ 45,635

	December 31, 2009			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Debt securities of U.S. government-sponsored entities	$ 43,800	$ 29	$ (9)	$ 43,820
Commercial paper	4,547		(1)	4,546
Total	$ 48,347	$ 29	$ (10)	$ 48,366

The Company had no realized gains or losses on its available-for-sale marketable securities for the years ended December 31, 2010, 2009 and 2008, respectively.

As of December 31, 2010, all of the Company s available-for-sale marketable securities had contractual maturities of one year or less.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Property and Equipment

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

	December 31,	
	2010	2009
	(In thousands)	
Laboratory equipment	$ 16,390	$ 14,430
Computer equipment	3,961	2,377
Computer software internal use	1,335	986
Furniture and fixtures	2,662	2,655
Leasehold improvements	13,082	12,981
Construction in progress	269	19
	37,699	33,448
Less accumulated depreciation and amortization	(27,354)	(20,583)
Total	$ 10,345	$ 12,865

For the years ended December 31, 2010, 2009 and 2008, the Company recorded property and equipment depreciation and amortization expense of $7.0 million, $6.5 million and $4.9 million, respectively.

Note 5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2010	2009
	(In thousands)	
Accrued expenses	$ 1,365	$ 794
Accrued accounts payable	1,891	873
Accrued professional and other service fees	958	1,278
Accrued refunds	659	757
Accrued collaboration expense	395	962
Accrued taxes payable	180	605
Other current liabilities	136	103
Total	$ 5,584	$ 5,372

Accrued accounts payable includes expenses for invoices received but not processed. Accrued professional and other service fees include third-party billing and collections costs, legal expenses, accounting and audit fees and investor relations expenses. Accrued refunds include overpayments due to third-party payors.

Note 6. Collaboration and Commercial Technology Licensing Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. The Company recorded collaboration expenses of $2.2 million, $2.2 million and $1.4 million for the years ended December 31, 2010, 2009 and 2008, respectively, relating to services provided in connection with these agreements. In addition to these expenses, some of the agreements contain provisions for royalties from inventions resulting from these collaborations. The Company has specified options and rights relating to joint inventions arising out of the collaborations.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company is a party to various agreements under which it licenses technology on a non-exclusive basis in the field of human diagnostics. Access to these licenses enables the Company to process its laboratory tests for the Onco*type* DX tests. 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, 2010, 2009 and 2008 of $10.5 million, $10.1 million and $7.8 million, respectively, which were included in cost of product revenues.

At December 31, 2010, future fixed annual payments, exclusive of royalty payments, relating to the launch and commercialization of our Onco*type* DX breast and colon cancer tests totaled $2.3 million and were payable as follows:

	Oncotype DX Breast Cancer	Oncotype DX Colon Cancer	Total Fixed Future Annual Payments
		(In thousands)	
Payment Due:			
January 2011	$ 475	$ 200	$ 675
January 2012		300	300
January 2013		450	450
January 2014		450	450
January 2015		450	450
Total	$ 475	$ 1,850	$ 2,325

These payments are recorded in cost of product revenues as license fees. Expense for payments included in the table above is recorded ratably over the year before the relevant payment is due. If at any time the Company discontinues the sale of the products covered by the agreement, no future annual payments will be payable and the Company will have no further obligation under the applicable agreements.

Note 7. Commitments

Lease Obligations

In September 2005, the Company entered into a non-cancelable lease for 48,000 square feet of laboratory and office space that the Company currently occupies in Redwood City, California. In November 2010, the Company exercised an option to extend the term of the lease for an additional five years. The lease expires in March 2019. The agreement included lease incentive obligations of $834,000 that are being amortized on a straight-line basis over the life of the lease. In connection with original lease, the Company was required to secure a $500,000 letter of credit, which is classified as restricted cash on the consolidated balance sheets. Upon execution of the lease amendment, the Company agreed to pay a $317,000 cash security deposit, which is included in other assets on the consolidated balance sheets as

of December 31, 2010, in exchange for the release of the $500,000 letter of credit held as security under the original lease. The letter of credit was released in January 2011.

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. In November 2010, the Company exercised an option to extend the term of the lease for an additional five years. The lease expires in March 2018. The agreement included 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.

In October 2009, the Company entered into a non-cancelable agreement to lease an additional 30,500 square feet of office space near the locations the Company currently occupies. The lease expires in March 2018, with an option for the Company to extend the term of the lease for an additional five years. The agreement includes lease

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

incentive obligations of $307,000 which are being amortized on a straight-line basis over the life of the lease. In connection with this lease, the Company paid a $183,000 cash security deposit, which is included in other assets on the consolidated balance sheets.

In May 2010, the Company s European subsidiary entered into a non-cancelable lease for approximately 2,500 square feet of office space in Geneva, Switzerland. The lease commenced on June 1, 2010 and expires in May 2015. In connection with this lease, the Company paid a CHF 100,800 cash security deposit, which is classified as restricted cash on the consolidated balance sheets.

Rent expense under all operating leases amounted to $1.7 million, $1.2 million and $1.1 million for the years ended December 31, 2010, 2009 and 2008, respectively. Future non-cancelable commitments under these operating leases at December 31, 2010 were as follows:

	Annual Payments (In thousands)
Years Ending December 31,	
2011	$ 2,443
2012	2,787
2013	2,920
2014	3,003
2015 and thereafter	10,055
Total minimum payments	$ 21,208

Note 8. Capital Stock

Common Stock

As of December 31, 2010, the Company had 29,007,564 shares of common stock outstanding. Shares of common stock reserved for future issuance as of December 31, 2010 were as follows:

	Number of Shares (In thousands)
Shares to be issued upon exercise of outstanding stock options	5,322
Shares available for future stock option grants	3,832
Shares of common stock reserved for future issuance	9,154

Note 9. 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. 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. The Company initially reserved 5,000,000 shares of the Company s common stock for issuance under the 2005 Plan, effective upon the closing of the Company s initial public offering on October 4, 2005. On June 8, 2009, the Company s stockholders approved an amendment to the 2005 Plan to increase the shares reserved for issuance under the 2005 Plan by 3,980,000 shares. The amended and restated plan also extends the term under which awards may be granted under the 2005 Plan until January 27, 2019.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Restricted shares, stock units and stock appreciation rights granted under the 2005 Plan are governed by 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.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Option Activity

The following table summarizes option activity for the years ended December 31, 2010, 2009 and 2008:

	Shares Available for Grant	Outstanding Options: Number of Shares	Outstanding Options: Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
	(Share amounts in thousands)			(In years)	(In thousands)
Balance at December 31, 2007	2,084	3,920	$ 13.33		
Options granted	(1,191)	1,191	$ 17.96		
Options exercised		(279)	$ 6.01		
Options forfeited	167	(167)	$ 18.61		
2001 Plan shares expired	(4)				
Balance at December 31, 2008	1,056	4,665	$ 14.76		
Increase in shares reserved for issuance under the 2005 Plan	3,980				
Options granted	(348)	348	$ 19.82		
Options exercised		(220)	$ 7.90		
Options forfeited	109	(109)	$ 19.06		
Balance at December 31, 2009	4,797	4,684	$ 15.36		
Options granted	(1,265)	1,265	$ 16.90		
Options exercised		(327)	$ 9.13		
Options forfeited	300	(300)	$ 19.35		
Balance at December 31, 2010	3,832	5,322	$ 15.88	6.9	$ 30,728
Exercisable at December 31, 2010		3,313	$ 14.67	5.8	$ 23,349
Vested and expected to vest at December 31, 2010		5,120	$ 15.81	6.8	$ 29,942

The total intrinsic value of stock options exercised during the years ended December 31, 2010, 2009 and 2008 was $2.9 million, $2.8 million and $4.1 million, respectively. The total fair value of options vesting during the years ended December 31, 2010, 2009 and 2008 was $5.5 million, $10.2 million and $10.1 million, respectively.

Employee Stock-Based Compensation Expense

The Company values its stock option grants using the Black-Scholes option valuation model. The Company recorded employee stock-based compensation expense of $10.3 million, $10.2 million and $9.1 million for the years ended December 31, 2010, 2009 and 2008, respectively. Employee stock-based compensation expense was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are 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

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

outside directors of the Company. The following table presents the impact of employee stock-based compensation expense on selected statements of operations line items for the periods indicated:

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Cost of product revenues	$ 342	$ 364	$ 491
Research and development	2,881	3,098	2,913
Selling and marketing	3,086	3,171	2,622
General and administrative	4,035	3,522	3,112
Total	$ 10,344	$ 10,155	$ 9,138

As of December 31, 2010, total unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was $14.4 million. The Company expects to recognize this expense over a weighted-average period of 28 months.

Valuation Assumptions

Option valuation models require the input of highly subjective assumptions that can vary over time. The Company s assumptions regarding expected volatility are based on the historical volatility of the Company s common stock. 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 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,		
	2010	2009	2008
Expected volatility	52%	55%	58%
Risk-free interest rate	2.49%	2.33%	1.98%
Expected life of options in years	5.77	5.80	5.84
Weighted-average fair value	$ 8.61	$ 10.44	$ 9.79

Stock Options Granted to Non-employees

The Company grants stock options to non-employee consultants from time to time in exchange for services performed for the Company. The Company did not grant any stock options to non-employee consultants during the year ended December 31, 2010. During the years ended December 31, 2009 and 2008, the Company granted options to purchase 5,000 and 14,400 shares, respectively, to non-employee consultants. The fair value of these option grants was

determined using the Black-Scholes option pricing model. In general, the options vest over the contractual period of the respective consulting arrangements 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, 2010, 2009 and 2008, stock-based compensation expense related to these options was $15,000, $80,000 and $88,000, respectively.

Note 10. Income Taxes

The Company recorded an income tax benefit of $136,000 for the year ended December 31, 2010, compared to income tax expense of $560,000 for the year ended December 31, 2009 and an income tax benefit of $61,000 for the year ended December 31, 2008.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Income tax benefit for the year ended December 31, 2010 was principally comprised of the reversal of 2009 federal alternative minimum tax and 2009 other state income taxes, net of current year non-California state income taxes and foreign income taxes. The reversal of 2009 federal alternative minimum income tax resulted from the enactment of the Worker, Homeownership and Business Assistance Act of 2009 that expanded the use of net operating losses.

The difference in income tax expense between the provision at the statutory rate of the Company s income before tax and the provision actually recorded was primarily due to the utilization of net operating loss carryforwards, non-deductible stock-based compensation expense and the reversal of 2009 federal alternative minimum tax and 2009 other state income taxes. The State of California suspended the utilization of net operating loss carryforwards for the 2010, 2009 and 2008 tax years, but allowed full utilization of business credit carryforwards in 2010 and allowed 50% utilization in 2009 and 2008. Accordingly, the 2010 California tax provision was offset by the California business credit carryforwards.

Income tax expense for the year ended December 31, 2009 was principally comprised of California state income tax and, to a lesser extent, federal alternative minimum tax and foreign taxes. The difference in income tax expense between the provision at the statutory rate of the Company s loss before tax and provision actually recorded was primarily due to the non-deductible stock based compensation expenses. For federal tax purposes, the provision was offset by the net operating loss carry-forwards that reduce the federal regular tax expense to the alternative minimum tax amount.

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 reflected 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.

The components of the Company s income (loss) before income taxes were as follows:

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Domestic	$ 4,019	$ (8,921)	$ (16,150)
Foreign	133	70	
Total income (loss) before income taxes	$ 4,152	$ (8,851)	$ (16,150)

The components of the Company s income tax expense (benefit) were as follows:

	Year Ended December 31,

	2010	2009	2008
	(In thousands)		
Current expense (benefit):			
Federal	$ (128)	$ 58	$ (65)
State	(49)	484	4
Foreign	41	18	
Total income tax expense (benefit)	$ (136)	$ 560	$ (61)

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The income tax expense (benefit) differed from the amounts computed by applying the U.S. federal statutory income tax rate of 35% for the year ended December 31, 2010 and 34% for the years ended December 31, 2009 and 2008, respectively, to income (loss) before income taxes as a result of the following:

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Federal tax at statutory rate	$ 1,453	$ (3,009)	$ (5,491)
Stock-based compensation	2,427	2,859	1,927
Non-deductible meals and entertainment	450	504	472
Net operating losses not used (used)	(4,301)	(165)	3,093
Federal alternative minimum tax	(123)	123	
State tax, net of federal benefit	(32)	320	3
Other	(10)	(72)	(65)
Total income tax expense (benefit)	$ (136)	$ 560	$ (61)

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover recorded net deferred taxes in future periods. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets for the years ended December 31, 2010 and 2009, respectively. The Company intends to continue maintaining a full valuation allowance on its deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of these allowances. Should the actual timing differences differ from the Company s estimates, the amount of its valuation allowance could be materially impacted.

As of December 31, 2010 and 2009, the Company had deferred tax assets of approximately $60.1 million and $65.7 million, respectively, which have been fully offset by a valuation allowance. The net valuation allowance decreased by approximately $5.7 million and increased by approximately $1.3 million during the years ended December 31, 2010 and 2009, respectively. Deferred tax assets primarily relate to net operating loss and tax credit carryforwards.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	December 31,	
	2010	2009
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 46,084	$ 49,917
Research tax credits	4,675	6,509
Fixed assets	3,404	3,278
Capitalized costs	928	1,196
Other	4,966	4,801
Total deferred tax assets	60,057	65,701
Valuation allowance	(60,057)	(65,701)
Net deferred tax assets	$	$

New California tax legislation enacted on February 20, 2009 provides for the election of a single sales apportionment formula beginning in 2011. The Company anticipates it will elect the single sales apportionment method. The use of this method has been reflected in the carrying value of California deferred tax assets reflected in the table above.

As of December 31, 2010, the Company had federal and state net operating loss carryforwards of approximately $115.0 million and $130.0 million, respectively, and federal and state research and development tax credit carryforwards of approximately $4.0 million and $2.3 million, respectively. The federal and state net operating loss and federal tax credit carryforwards will expire at various dates beginning in 2016 if not utilized. The state tax credit carryforwards have no expiration date.

The Company tracks a portion of its deferred tax assets attributable to stock option benefits in a separate memorandum account. Therefore, these amounts are no longer included in the Company s gross or net deferred tax assets. The benefit of these stock options will not be recorded in equity unless it reduces taxes payable. As of December 31, 2010, the portion of the federal and state net operating loss related to stock option benefits was approximately $4.3 million.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations as defined under Sections 382 and 383 of 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 had $768,000, $685,000 and $575,000 of unrecognized tax benefits as of December 31, 2010, 2009 and 2008, respectively. The following table summarizes the activity related to unrecognized tax benefits:

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
Balance at January 1	$ 685	$ 575	$ 413
Increase (decrease) related to prior year tax positions	19	(35)	9
Increase related to current year tax positions	64	145	153
Balance at December 31	$ 768	$ 685	$ 575

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 recognizes accrued interest and penalties related to unrecognized tax benefits in as part of its income tax provision in its consolidated statements of operations. For the year ended December 31, 2010, the Company recognized $11,000 in interest related to unrecognized tax benefits. The Company did not recognize any interest or tax related penalties for the years ended December 31, 2009 and 2008, respectively. All tax years from 2001 forward remain subject to future examination by federal, state and foreign tax authorities.

Note 11. Selected Quarterly Financial Data (Unaudited)

The following table contains selected unaudited consolidated statements of operations information for each of the fiscal quarters in 2010 and 2009. 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)		
2010:				
Total revenues	$ 41,229	$ 43,439	$ 46,317	$ 47,116
Product revenues	40,266	42,514	45,773	46,317
Cost of product revenues	8,966	8,107	8,853	8,707
Net income (loss)	(1,932)	865	3,670	1,685
Basic net income (loss) per common share	$ (0.07)	$ 0.03	$ 0.13	$ 0.06
Diluted net income (loss) per common share	$ (0.07)	$ 0.03	$ 0.12	$ 0.06
2009:				
Total revenues	$ 33,896	$ 36,552	$ 39,517	$ 39,583
Product revenues	33,427	35,191	38,910	39,053
Cost of product revenues	7,827	7,891	8,301	8,543
Net loss	(4,625)	(3,943)	(502)	(341)
Basic net loss per common share	$ (0.16)	$ (0.14)	$ (0.02)	$ (0.01)
Diluted net loss per common share	$ (0.16)	$ (0.14)	$ (0.02)	$ (0.01)

The quarterly increases in product revenues during 2010 and 2009 and cost of product revenues during 2009 were primarily attributable to increased adoption of the Onco*type* DX breast cancer test by physicians and increased reimbursement for this test by third-party payors. The decrease in cost of product revenues during 2010 reflected cost efficiencies and the discontinuance of payments under an existing license fee agreement due to the abandonment of a patent by the licensor.

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.

For all quarters presented in 2009 and for the quarter ended March 31, 2010, basic and diluted net income (loss) per common share are identical as common equivalent shares are excluded from the calculation because their effect is anti-dilutive.

Table of Contents

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, 2010. 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, 2010, 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:

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Genomic Health, Inc.

We have audited Genomic Health, Inc. s internal control over financial reporting as of December 31, 2010, 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, 2010, 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, 2010 and 2009, and the related statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2010 and our report dated March 11, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 11, 2011

93

Table of Contents

(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 2011 Annual Meeting of Stockholders to be held on June 9, 2011, 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 and Ethics that applies to all of our officers and employees, including our President and Chief Executive Officer, our Chief Financial Officer and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics 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 our President and Chief Executive Officer, our 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: Chief Financial Officer, 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, Dr. Fred E. Cohen and Ms. Ginger L. Graham. 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 Director Compensation and Executive Compensation contained in the Proxy Statement.

Table of Contents

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 Executive Compensation 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 Election of Directors 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 Ratification of the Appointment of Independent Registered Public Accounting Firm 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, 2010, 2009, and 2008.

All other 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).

Table of Contents

Exhibit No.	Description of Document
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).
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).
10.10#	Amended and Restated Genomic Health, Inc. 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 June 30, 2009).
10.11#	Form of Stock Option Agreement (incorporated by reference to exhibit 10.2 filed with the Company s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2009).

Table of Contents

Exhibit No.	Description of Document
10.12	Lease dated October 1, 2009 between the Company and Metropolitan Life Insurance Company (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, 2009).
10.13*	First Amendment to Lease dated November 30, 2010 between the Company and Metropolitan Life Insurance Company.
10.14*	Second Amendment to Lease dated November 30, 2010 between the Company and Metropolitan Life Insurance Company.
10.15*#	Form of Global Restricted Stock Unit Agreement under the Company s 2005 Stock Incentive Plan.
12.1*	Statement Regarding Computation of Ratios.
21.1*	List of Subsidiaries.
23.1*	Consent of independent registered public accounting firm.
24.1*	Power of Attorney (see page 99 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.
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 No. 34-47986, 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.

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.

Table of Contents

SCHEDULE II

GENOMIC HEALTH, INC.

VALUATION AND QUALIFYING ACCOUNTS
Years Ended December 31, 2010, 2009 and 2008

	Balance at Beginning of Period	Expenses	Deductions	Balance at End of Period
		(In thousands)		
Allowance for Doubtful Accounts:				
Year ended December 31, 2010	$ 545	$ 2,231	$ 2,096	$ 680
Year ended December 31, 2009	$ 881	$ 1,441	$ 1,777	$ 545
Year ended December 31, 2008	$ 133	$ 1,343	$ 595	$ 881

Table of Contents

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 11, 2011

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, Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2011
/s/ Dean L. Schorno Dean L. Schorno	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 11, 2011
/s/ Randal W. Scott, Ph.D. Randal W. Scott, Ph.D.	Executive Chairman of the Board of Directors	March 11, 2011
/s/ Julian C. Baker Julian C. Baker	Director	March 11, 2011
/s/ Brook H. Byers	Director	March 11, 2011

Brook H. Byers		
/s/ Fred E. Cohen, M.D., D. Phil.	Director	March 11, 2011
Fred E. Cohen, M.D., D. Phil.		
/s/ Samuel D. Colella	Director	March 11, 2011
Samuel D. Colella		

Table of Contents

Signature	Title	Date
/s/ Ginger L. Graham Ginger L. Graham	Director	March 11, 2011
/s/ Randall S. Livingston Randall S. Livingston	Director	March 11, 2011
/s/ Woodrow A. Myers Jr., M.D. Woodrow A. Myers Jr., M.D.	Director	March 11, 2011

Table of Contents

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