GENOMIC HEALTH INC
Form 10-K
March 16, 2007

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

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended: December 31, 2006

OR

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

Commission File Number: 000-51541

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

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

(650) 556-9300
(Registrant s telephone number, including area code)

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

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

Common Stock **The NASDAQ Stock Market LLC**

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o

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, 2006, the aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant was approximately $288.5 million, based on the closing price of the common stock as reported on the NASDAQ Global Market for that date.

There were 24,563,212 shares of the registrant s Common Stock issued and outstanding on February 28, 2007.

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 2007 Annual Meeting of Stockholders to be held on June 12, 2007.

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PART I

ITEM 1. ***Business***.

This Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this Report, the words expects, anticipates, intends, estimates, plans, believes, and simila expressions are intended to identify forward-looking statements. These are statements that relate to future periods and include statements about our expectation that, for the foreseeable future, substantially all of our revenues will be derived from Oncotype DX; the factors we believe to be driving demand for Oncotype DX and our ability to sustain such demand; our expectation that our research and development expense levels will remain high as we seek to enhance Oncotype DX and develop new tests; our expectation that our general and administrative and sales and marketing expenses will increase and our anticipated uses of those funds; our expectations regarding capital expenditures; the factors that may impact our financial results; the extent and duration of our net losses; our ability to comply with the requirements of being a public company; our ability to attract and retain experienced personnel; the impact changes in healthcare policy or regulation could have on our business; the adequacy of our product liability insurance; our ability to recognize revenues other than on a cash basis and when we expect we will recognize a majority of revenues upon providing tests; the level of investment in our sales force; the capacity of our commercial laboratory to process tests and our expected expanded capacity; our dependence on collaborative relationships and the success of those relationships; whether any tests will result from our collaborations; our belief that clinical results support our development of a test for colon cancer; the applicability of clinical results to actual outcomes; our estimates and assumptions with respect to disease incidence; the ability of our test to impact treatment decisions; the economic benefits of our test to the healthcare system, our compliance with federal, state and foreign regulatory requirements; our expectation that product revenues will increase; how we intend to spend our existing cash and cash equivalents and how long we expect our existing cash to last; our expected future sources of cash; our plans to borrow additional amounts under existing or new financing arrangements; the potential impact resulting from the regulation of Oncotype DX by the U.S. Food and Drug Administration, or FDA, and our belief that Oncotype DX is properly regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA; our beliefs regarding reimbursement for Medicare inpatients; our plans to pursue reimbursement on a case-by-case basis; our ability, and expectations as to the amount of time it will take, to achieve successful reimbursement from third-party payors and government insurance programs; our intent to enter into additional foreign distribution arrangements; the factors that we believe will drive the establishment of coverage policies; the impact of changing interest rates; the amount of future revenues that we may derive from Medicare patients or categories of patients; increases in patient and physician demand resulting from our direct sales approach; plans for enhancements of Oncotype DX to address different patient populations of breast cancer or to report single gene results; plans for, and the timeframe for the development and commercial launch of, future tests addressing multiple cancers; our expectation regarding when we may move another potential test into development; the outcome or success of clinical trials; our intellectual property and our strategies regarding filing additional patent applications to strengthen our intellectual property rights; the impact of accounting pronouncements and our critical accounting policies, estimates, models and assumptions on our financial results; our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing; 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 reimbursement for our existing test and any future tests we may develop; the risks and uncertainties associated with the regulation of our test by FDA; the ability to compete against third parties; our ability to obtain capital when needed; and our history of operating losses. These

forward-looking statements speak only as of the date hereof. The Company expressly disclaims any obligation or undertaking to update to any forward-looking statements contained herein to reflect any change in the Company s expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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

All references to Genomic Health, we, us, or our mean Genomic Health, Inc.

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, Inc. was formed as a Delaware corporation in August 2000. We are a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. In January 2004, we launched our first test under the brand name Onco*type* DX for early stage breast cancer patients. We believe that Onco*type* DX is the first genomic test with clinical evidence supporting its ability to predict the likelihood of cancer recurrence, the likelihood of patient survival within 10 years of diagnosis and the likelihood of chemotherapy benefit. Our initial test is focused on patients with early stage, node negative, or N−, estrogen receptor positive, or ER+, breast cancer who will be treated with tamoxifen, a frequently used hormonal therapy. Of the 240,000 patients who were expected to be diagnosed with breast cancer in the United States in 2006, approximately half were predicted to be early stage breast cancer patients that are N−and ER+. Many of the diagnostic factors currently used in connection with early stage breast cancer are subjective, have limited capability to predict future cancer recurrence and are not useful in predicting chemotherapy benefit. We believe that the use of Onco*type* DX can provide a deeper understanding of each patient s breast cancer and therefore should result in better informed and more appropriate treatment decisions.

We developed Onco*type* DX using a multi-step approach, conducting clinical studies on tumor specimens from more than 2,600 breast cancer patients. Our technology provides quantitative gene expression information for each patient s tumor, which we refer to as an oncotype. When an oncotype is correlated with known clinical outcomes, it can be useful in predicting the likelihood of an individual patient s tumor behavior. Onco*type* DX for breast cancer utilizes a 21-gene panel whose composite gene expression profile can be represented by a single quantitative score, which we call a Recurrence Score. The higher the Recurrence Score, the more aggressive the tumor and the more likely it is to recur. The lower the Recurrence Score, the less aggressive the tumor and the less likely it is to recur. Onco*type* DX has been clinically validated for N−, ER+, tamoxifen-treated breast cancer patients by two large independent studies. Moreover, we have demonstrated that the Recurrence Score correlates with chemotherapy benefit, and we are undertaking further studies to support this finding. Onco*type* DX is commercially available at a list price of $3,460 through our 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. Since the commercial launch of Onco*type* DX in 2004 through December 31, 2006, over 21,500 tests had been delivered for use in treatment planning by more than 5,000 physicians.

Substantially all of our tests to date have been delivered to physicians in the United States. We believe that each year we may experience decreased demand for our test in the summer months of July and August, which may be attributed to physicians, surgeons and patients scheduling vacations during this time. One major customer accounted for approximately 47% of our product revenue for the year ended December 31, 2006; no revenue from this customer was recorded in 2005. Another major customer accounted for approximately 4% and 11% of our revenue in 2006 and 2005, respectively.

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

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2006, approximately 1.4 million people in the United States were expected to be diagnosed with cancer. Common types of cancer include breast, prostate, lung and colon. Cancers are difficult to treat because each type responds differently to treatments, depending upon the individual and the type and location of the cancer.

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

Once a pathologist diagnoses cancer, the patient s physician determines the stage of the cancer based on further analysis of the patient s condition using a variety of clinical measures, including the 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 existing tests are also evaluated and considered.

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

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

Use of Genomics to Understand Cancer

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

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

disease.

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.

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

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

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

Our Solution

Our genomic-based diagnostic approach correlates gene expression information to clinical outcomes and provides information designed to improve treatment decisions for cancer patients. 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 with known clinical outcomes. Once we have established and validated a test, we can then analyze a patient s tumor and correlate the result to known clinical outcomes. As a result, each tumor s gene expression can be quantified and correlated with responsiveness to therapy or the likelihood of cancer recurrence or progression. Onco*type* DX, our first clinically validated product, uses this quantitative molecular pathology approach to provide an individualized analysis of each patient s tumor.

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

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

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

Improved Quality of Treatment Decisions. We believe our approach to genomic-based cancer analysis improves the quality of cancer treatment decisions by providing an individualized analysis of each patient s tumor that is correlated to clinical outcome. Our approach represents a substantial departure from existing approaches to treatment, which often use subjective, anatomic and qualitative factors to determine treatments. Onco*type* DX has been shown in clinical studies to classify many patients into recurrence risk categories different from classifications based on current guidelines. Thus, our solution enables patients and physicians to make more informed decisions about treatment risk-benefit considerations and, consequently, design an individualized treatment plan.

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Improved Economics of Cancer Care. We believe that improving the quality of treatment decisions can result in significant economic benefits. In early stage breast cancer, our data shows that many patients are misclassified as high or low risk under existing treatment guidelines. Many low risk patients misclassified as high risk receive toxic and expensive chemotherapy treatment regimens. Chemotherapy and related costs may exceed $20,000, as compared to Onco*type* DX s list price of $3,460. On the other hand, some high risk patients misclassified as low risk are not provided chemotherapy treatment, possibly necessitating future treatment costing up to $50,000 or more if the cancer recurs.

Oncotype DX

Onco*type* DX uses quantitative molecular pathology to improve cancer treatment decisions. We offer Onco*type* DX as a clinical laboratory test, where we analyze tumor tissue samples in our laboratory and provide physicians with genomic information specific to the patient s tumor. Early stage breast cancer is the first patient population where we have commercialized a genomic test that has been shown clinically to predict the likelihood of cancer recurrence, the likelihood of patient survival within 10 years of diagnosis and the likelihood of chemotherapy benefit.

Our technology provides quantitative gene expression information for each patient s tumor, which we refer to as an oncotype. When an oncotype is correlated with known clinical outcomes, it can be useful in predicting the likelihood of an individual patient s tumor behavior. This allows the physician and patient to address key issues such as risk of disease recurrence or progression, likelihood of long-term survival and potential benefit from chemotherapy or other treatments. In breast cancer, we developed our gene panel by narrowing the field of the approximately 25,000 human genes down to 250 cancer-related genes through review of existing research literature and computer analysis of genomic databases. We evaluated the 250 genes in three independent clinical studies to identify a 21-gene panel whose composite gene expression profile can be represented by a single quantitative score, which we call a Recurrence Score. The higher the Recurrence Score, the more aggressive the tumor and the more likely it is to recur. The lower the Recurrence Score, the less aggressive the tumor and the less likely it is to recur. Moreover, we have demonstrated that the Recurrence Score also correlates with the likelihood of chemotherapy benefit, and we are undertaking further studies to support this finding.

Oncotype DX for Breast Cancer

Approximately 240,000 new cases of breast cancer were diagnosed in the United States in 2006. Following diagnosis, a physician determines the stage of the breast cancer by examining the following:

- the size of the tumor,
- node status, referred to as node positive, or N+, where the tumor has spread to the lymph nodes, and node negative, or N−, where the tumor has not spread to the lymph nodes, and
- the extent to which the cancer has spread to other parts of the body.

Breast cancer tumors are classified as stage I, II, III or IV. Stage I and II are generally referred to as early stage breast cancer, and stage III and IV are generally referred to as late-stage breast cancer. Standard treatment guidelines weigh the stage of the cancer and additional factors to predict cancer recurrence and determine treatment protocol such as:

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

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

the age of the patient, and

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

Because these diagnostic factors have limited capability to predict future recurrence and chemotherapy benefit, and some are subjective, a large percentage of early stage breast cancer patients are classified as high risk.

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

We believe that Onco*type* DX is the first genomic test that has clinical evidence supporting its ability to predict the likelihood of cancer recurrence, the likelihood of patient survival within 10 years of diagnosis and the likelihood of chemotherapy benefit in early stage, N−, ER+ breast cancer patients treated with tamoxifen. Onco*type* DX is currently available at a list price of $3,460. We accept orders from all 50 states through our commercial laboratory located in Redwood City, California. Our laboratory is licensed under CLIA and accredited by CAP.

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

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

Clinical Development and Validation of Oncotype DX

Clinical Development of the Oncotype DX Recurrence Score

We developed Onco*type* DX using a multi-step approach, conducting clinical studies on tumor specimens from more than 2,600 breast cancer patients. First, we developed methods, using RT-PCR, to quantify the expression of hundreds of genes in RNA isolated from fixed paraffin embedded tumor tissue. We then selected 250 cancer-related genes using computer analysis of genomic databases and our knowledge of cancer pathways. Third, we performed three independent breast cancer clinical studies in a total of 447 patients with known clinical outcomes to test the relationship between the expression of the 250 cancer-related genes and recurrence. Two of these studies were

conducted at Providence Saint Joseph Medical Center and Rush University Medical Center, using samples from patients with N− and N+ tumors who received tamoxifen, chemotherapy or both. A third study was conducted in our specific target population of N−, ER+ patients treated with tamoxifen.

From these studies we selected a panel of 21 genes, comprised of 16 cancer-related genes and five reference genes, with which we developed the Recurrence Score utilizing a number of statistical approaches. The Recurrence

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Score is obtained by first normalizing the expression of the cancer-related genes against the reference genes and then applying the Recurrence Score formula to calculate a single score scaled between 0 and 100.

Clinical Validation of Prediction of Recurrence and Survival in N−, ER+ Patients Treated with Tamoxifen

Our clinical validation studies were designed to answer two questions about the utility of the Recurrence Score when N−, ER+ breast cancer patients treated with tamoxifen make additional treatment decisions. First, we wanted to test whether Onco*type* DX could differentiate patients with a high likelihood of recurrence from patients with a low likelihood of recurrence. Second, we wanted to expand these results with a second study to demonstrate success in predicting breast cancer survival in a community hospital setting.

Oncotype DX Predicts the Likelihood of Recurrence. Our initial validation study was performed in 2003 in collaboration with the NSABP to determine whether Onco*type* DX predicts the likelihood of breast cancer recurrence. This study, which was reported at the San Antonio Breast Cancer Conference in December 2003 and published in *The New England Journal of Medicine* in December 2004, evaluated the ability of Onco*type* DX to quantify the likelihood of breast cancer recurrence over 10 years. The study involved 668 patients who were enrolled in the NSABP Study B-14 between 1982 and 1988. Each patient sample was analyzed in a blinded fashion and the results provided back to the NSABP through a neutral party at the University of Pittsburgh for analysis. The Recurrence Score was used to prospectively define the following three risk groups based on our clinical development studies described above:

- a low risk group, with a Recurrence Score of less than 18, classified 51% of patients with an average recurrence rate of 6.8%;

- an intermediate risk group, with a Recurrence Score equal to or greater than 18 but less than 31, classified 22% of the patients with an average recurrence rate of 14.3%; and

- a high risk group, with a Recurrence Score greater than 31, which included 27% of the patients with an average recurrence rate of 30.5%.

The Recurrence Score was able to assign patients into high and low risk groups ($p<0.001$) and, when the Recurrence Score was examined together with age and tumor size in a multivariate analysis, only the Recurrence Score remained a significant predictor of patient outcome ($p<0.001$). A p-value indicates the probability that the result obtained in a statistical test is due to chance rather than a true relationship between measures. A small p-value, generally less than 0.05, or $p<0.05$, indicates that it is very unlikely that the results were due to chance. In this study we also demonstrated that the likelihood of distant recurrence at 10 years increased continuously as the Recurrence Score increased, with a range from about 3% recurrence for a Recurrence Score of zero to greater than 30% recurrence for patients in the high Recurrence Score category. In addition, in subgroup analysis of various ages, tumor sizes and pathology grade, the Recurrence Score remained a consistent predictor of distant recurrence.

Oncotype DX Predicts the Likelihood of Breast Cancer Survival in a Community Hospital Setting. In collaboration with Northern California Kaiser Permanente, we conducted a large, case-control, epidemiological study of breast cancer patients diagnosed from 1985 to 1994 at 14 Northern California Kaiser hospitals. This study was initially reported at the San Antonio Breast Cancer Conference in December 2004 and further detailed results were presented at the annual meeting of the American Society of Clinical Oncology, or ASCO, in May 2005 and published in the *Journal of Clinical Oncology* in May 2006. Patients who died of breast cancer, or the cases, were matched with up to three controls based on each case s age, race and ethnicity, tamoxifen treatment, facility and diagnosis year. Controls had to be alive at the time of the corresponding case s death in order to compare outcomes and availability of follow-up for those patients alive at time of each case death. To be eligible, patients had to be N−, less than 75 years old and not have received adjuvant chemotherapy. Among a potentially eligible population of 4,964 patients, we

identified 220 eligible cases and 570 matched controls. Approximately one-third of the study patients were treated with tamoxifen. This study was performed to confirm that the Recurrence Score predicts breast cancer survival at 10 years in ER+ patients treated with tamoxifen. The likelihood of breast cancer survival at 10 years was more than five fold higher for patients in the pre-defined low Recurrence Score group when compared to patients in the pre-defined high Recurrence Score group ($p<0.003$). With respect to the group of ER+ patients

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treated with tamoxifen, the absolute risk of breast cancer death at 10 years in the pre-specified risk groups was 2.8% for the low risk group, 10.7% for the intermediate risk group and 15.5% for the high risk group. Additionally, in the larger population of ER+ patients untreated with tamoxifen, the Recurrence Score was also statistically significantly associated with breast cancer death at 10 years ($p<0.025$). This study, conducted in a community hospital setting, demonstrates that the Recurrence Score is independently associated with risk of breast cancer death and is able to identify subgroups of patients according to low, intermediate and high risk of death at 10 years.

Additional Questions Addressed by Further Studies

Additional studies were conducted to investigate three clinical and scientific questions:

How do patients in the different Recurrence Score risk groups respond to tamoxifen plus chemotherapy versus tamoxifen alone?

Does the Recurrence Score predict the likelihood of recurrence, the benefit from tamoxifen or both?

Does the Recurrence Score apply to untreated ER− patients and untreated ER+ patients?

Oncotype DX Predicts the Likelihood of Chemotherapy Benefit. We conducted a study in 2004 with the NSABP to determine whether Onco*type* DX is predictive of the likelihood of chemotherapy benefit. This study, which was reported initially at the San Antonio Breast Cancer Conference in December 2004 and further detailed results were presented at ASCO s annual meeting in May 2005, included 651 patients from the NSABP Study B-20 with N−, ER+ breast cancer enrolled from 1988 to 1993. Of these patients, 227 were treated with tamoxifen alone and 424 were treated with tamoxifen plus chemotherapy. The results of this study demonstrated that low risk patients, as defined by the Recurrence Score, had a 96% recurrence-free survival rate at 10 years without chemotherapy compared with a 95% survival rate with chemotherapy, and intermediate risk patients as defined by the Recurrence Score had a 90% survival rate without chemotherapy compared with an 89% rate with chemotherapy. High risk patients as defined by the Recurrence Score had a 60% survival rate without chemotherapy compared with an 88% rate with chemotherapy ($p<0.001$). These results demonstrate that Onco*type* DX not only quantifies recurrence and survival risk but also correlates with the likelihood of chemotherapy benefit in early stage N−, ER+ breast cancer patients.

Oncotype DX Predicts Likelihood of Recurrence Because it Predicts both Prognosis and Tamoxifen Benefit. In 2004, we conducted an expanded study with the NSABP Study B-14 population to determine whether Onco*type* DX captures information regarding likelihood of distant recurrence, tamoxifen benefit, or both. This study s conclusions were initially reported at the San Antonio Breast Cancer Conference in December 2004. Further detailed results were presented at ASCO s annual meeting in May 2005 and published in the *Journal of Clinical Oncology* in May 2006. The study included 645 patients with N−, ER+ breast cancer enrolled from 1982 to 1988, 355 of whom were given placebos and 290 of whom where treated with tamoxifen. The results of this study demonstrated that Onco*type* DX predicts the likelihood of distant disease recurrence in tamoxifen-treated patients with N−, ER+ breast cancer because it captures both prognosis and tamoxifen benefit. Furthermore, this study of Onco*type* DX demonstrates that low and intermediate risk patients as defined by the Recurrence Score had the largest benefit of tamoxifen and high risk patients as defined by the Recurrence Score had minimal benefit of tamoxifen. The quantitative levels of ER, as defined by Onco*type* DX, varied by over two-hundred fold within the ER+ population and increasing levels of quantitative ER gene expression correlated with increasing tamoxifen benefit. Finally, Onco*type* DX was able to discriminate between high and low risk patients in a subset of patients not treated with tamoxifen.

Results Were Inconclusive as to Whether Oncotype DX Predicts Likelihood of Recurrence in a Mixed Population of N−, Untreated Patients. In 2003, we conducted a trial with The M.D. Anderson Cancer Center to test the predictive power of Onco*type* DX in untreated breast cancer patients who were either ER−or ER+. This study was first reported

at the San Antonio Breast Cancer Conference in December 2003 and published in *Clinical Cancer Research* in May 2005. Out of a pool of over 4,000 N− patient tissue samples, only 149 patients were untreated and had a sufficient tissue sample and RNA available to make them eligible for the study. The study population differed significantly from the NSABP Study B-14 treatment arm used for our initial validation study in that none of the patients were treated with tamoxifen, and the population included ER− and ER+ patients. This

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study did not demonstrate a significant predictive power for Onco*type* DX in untreated N patients. Importantly, it also did not demonstrate the expected predictive power for other known predictive factors. For example, tumor grade inversely correlated with expected outcomes. Subsequent evaluations of Onco*type* DX in the NSABP Study B-14 placebo arm using samples from untreated ER+ patients and in the Kaiser Permanente population-based study using samples from untreated ER+ and ER− patients demonstrated a correlation between the Recurrence Score and recurrence and survival. These results were reported at the San Antonio Breast Cancer Conference in December 2004 and ASCO s annual meeting in May 2005.

Health Economic Benefits of Oncotype DX

We are sponsoring third-party studies conducted by researchers affiliated with academic institutions to examine the health economic implications of Onco*type* DX. Two such studies, one of which was published in *The American Journal of Managed Care* in May 2005, analyzed data from patients in the NSABP Study B-14 multi-center clinical trial to compare risk classification based on guideline criteria from the National Comprehensive Cancer Network, or NCCN, to risk classification by Onco*type* DX. Of the 668 patients in the NSABP study population, NCCN guidelines classified 615, or 92%, as high risk and 53, or 8%, as low risk. Of the 615 patients classified as high risk by NCCN, Onco*type* DX classified 49% as low risk, 22% as intermediate risk and 29% as high risk. Of the 53 patients that NCCN classified as low risk, Onco*type* DX classified 6% as high risk, 22% as intermediate risk and 72% as low risk. In each case, Onco*type* DX provided a more accurate classification of risk than the NCCN guidelines as measured by 10 year distant recurrence free survival.

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

New Product Development

We developed Onco*type* DX using the following multi-phased clinical development platform that we intend to use in developing future products for breast and other cancers:

Early Development Phase. In this phase, we establish a product definition and research plan. Our research team initiates the clinical research program with computer-based screening of the approximately 25,000 genes in the human genome to select candidate genes. The gene selection process uses genomic databases and knowledge of key cancer and drug related pathways. We use internally developed software for optimization and rapid selection of target DNA sequences in order to develop quantitative molecular pathology assays for each gene. To date, we have compiled a library of over 1,300 individual gene tests for use in multiple product opportunities. We secure access to archival tumor biopsy samples for feasibility studies as well as archival tumor biopsy samples correlated with clinical data for gene identification studies. The goal of these studies is to identify genes that correlate with a specific clinical outcome prior to moving the program into development.

Development Phase. 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

to develop the best quantitative correlation to the target clinical outcome. With a gene panel and quantitative methodology established, we then finalize all of the remaining assay parameters. For example, for Onco*type* DX we tested and verified protocols for RNA extraction and amplification, automated chemistry and reagent quality control and handling to establish a reproducible, scaleable process. Once the genes, assay chemistry, automation and analysis specifications are finalized, tested and verified, we begin clinical validation.

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Validation Phase. 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. These studies are conducted with a different set of archival patient specimens to verify that the test correlates with the predicted clinical outcome in an independent patient population. Since we control the quality and reproducibility of our assays using FPE tissues, we are able to conduct large validation studies with archived samples with years of clinical outcomes. This allows validation studies to be performed more rapidly than would be the case with techniques that require fresh tissue, which must be newly collected and need many years of follow up before study results can be obtained.

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. Multiple clinical studies can also be useful for driving adoption and reimbursement by physicians and payors. Such studies may include prospective studies to verify that our test is changing physician behavior as well as testing a commercial product in new populations. The results of a study conducted by oncologists at the Rocky Mountain Cancer, which were presented at the 2005 San Antonio Breast Cancer Symposium, confirmed that the Recurrence Score has an impact on treatment decisions made by physicians in current clinical practices. Additional studies to support the test s clinical utility and broaden its use are currently ongoing.

Our Product Pipeline

Over 600,000 treatment decisions were expected to be made in the United States in 2006 for patients diagnosed with early stages of breast, colon, prostate, renal cell and lung cancers and melanoma. Early stage cancers are often treated with adjuvant treatments that are administered in conjunction with primary therapy, such as surgery and radiation, intended to prevent the recurrence of a particular cancer. The early stage patient population is generally the larger treatment population for most cancers. While our products under development focus on early stage disease, we consider product opportunities in late-stage disease when appropriate.

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Product Development Opportunities in Breast Cancer

The following table describes our current breast cancer product and our product opportunities:

Breast Cancer Products	Breast Cancer Population	2006 Estimated Treatment Decisions in the United States	Anticipated Product Attributes	Product Stage
Onco*type* DX	N−, ER+	130,000	Recurrence Chemotherapy benefit	Commercial
			Chemotherapy or other therapeutic regimens benefit	Product Expansion
	Single gene reporting N−, ER+	130,000	Chemotherapy or other therapeutic regimens benefit	Product Expansion
	N+	70,000	Recurrence Chemotherapy or other therapeutic regimens benefit	Product Expansion
	Single gene reporting N+	70,000	Chemotherapy or other therapeutic regimens benefit	Product Expansion
Onco*type* DX Second Generation	N−, ER+ and	200,000(1)	Enhanced recurrence	Early Development
	N+		Enhanced chemotherapy benefit	
New Product Opportunities	N−, ER−	30,000	Taxane benefit(2)	Early Development
			Chemotherapy benefit Recurrence	
	N+	70,000(3)	Taxane benefit Chemotherapy benefit	Early Development
	N−, ER+	130,000(4)	Taxane benefit	Early Development

(1) Represents the sum of the 130,000 estimated treatment decisions in 2006 for N−, ER+ patients and 70,000 estimated treatment decisions in 2006 for N+ breast cancer patients listed above.

(2) Taxanes are a class of chemotherapy drugs that are commonly used for breast cancer.

(3) This figure is the same as the 70,000 treatment decisions listed above.

(4) This figure is the same as the 130,000 treatment decisions listed above.

Oncotype DX

We are conducting clinical studies with Onco*type* DX with the goals of expanding the applications in which it may be used and improving certain product features. Approximately 70,000 patients were expected to be diagnosed in the United States in 2006 with N+ breast cancer and many may not benefit from chemotherapy or may have other health issues that increase the risk of chemotherapy treatment. Our early clinical research studies with Rush University Medical Center and Providence Saint Joseph Medical Center support further investigation of Onco*type*

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DX for prediction of recurrence in this patient population. Node positive studies are ongoing with additional studies planned for 2007 which, if successful, may support the launch of a commercial product in 2008. Additionally, we believe that gene scores reported as individual gene scores in addition to the Recurrence Score 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 studies of the NSABP Study B-14 population. We are conducting additional studies to evaluate the clinical utility of individual Onco*type* DX genes and, if successful, plan to provide single gene results for ER and progesterone receptor, or PR, gene expression in test results by the end of 2007.

Second Generation Oncotype DX

We are in the early development phase of investigating additional genes and gene combinations that may add to the predictive power of Onco*type* DX. A second generation product, if successful, could further refine and improve the classification of patients and result in better information for treatment decisions. We have identified multiple genes through research and development studies that, in varying combinations, may provide improved prediction of recurrence risk and likelihood of chemotherapy benefit.

Recurrence and Benefit Test for N−, ER− Breast Cancer

We are in the early development phase for a product to predict the likelihood of recurrence and chemotherapy benefit in N−, ER− breast cancer patients. This population was expected to represent approximately 30,000 patients in the United States in 2006. To date, we have conducted several clinical research studies that included N−, ER− breast cancer patients, and we plan to continue to explore opportunities in this population, including tests to better define ER− patients based on quantitative molecular pathology.

Taxane Benefit Test

We are also in the early development phase for a product to predict the likelihood of taxane benefit. Taxanes are a class of chemotherapy drugs that are used in addition to traditional chemotherapy regimens in some patients but have side effects and are most often used in patients with aggressive or later stage tumors. The potential population for this product includes the estimated 70,000 N+ breast cancer patients as well as N−, ER− patients at high risk and N− patients at high risk in the United States in 2006. We have developed a number of hypotheses and selected a gene panel to investigate this product opportunity further.

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Product Development Opportunities in Other Cancers

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

Product Opportunity	2006 Estimated Total Incidence in the United States	2006 Estimated Addressable Population	Anticipated Product Attributes	Product Stage
Colon Cancer	120,000	65,000	Recurrence Prediction of drug response	Development
Prostate Cancer	260,000	200,000	Progression Recurrence	Early Development
Renal Cell Cancer	40,000	25,000	Recurrence Prediction of drug response	Early Development
Non-small Cell Lung Cancer	160,000	45,000	Recurrence Prediction of drug response	Early Development
Melanoma	70,000	60,000	Recurrence Prediction of drug response	Early Development

Colon Cancer Recurrence and Response Test

In January 2007 we moved a potential test to predict the likelihood of recurrence and chemotherapy benefit in patients with early stage colon cancer from early development to development phase. Colon cancer was expected to affect approximately 120,000 individuals in the United States in 2006, of which approximately 65,000 early stage patients needed to decide whether or not to use chemotherapy for their cancer, as well as which chemotherapy to use. Only a small percentage of colon cancer patients are expected to have a survival benefit from additional treatment after surgery. We have developed an investigational 758-gene panel for colon cancer and have established a collaborative agreement with the NSABP, as well as other academic groups, to access colon tissue samples that have associated clinical outcome data. If successful, studies in 2007 may lead to a validation study in 2008, which could result in a commercial launch in 2009.

Prostate Cancer Progression and Recurrence Test

We are in the early development phase for a test to predict the likelihood of progression and recurrence of prostate cancer in early stage patients. Approximately 260,000 men were expected to be diagnosed with prostate cancer in the United States in 2006, approximately 200,000 of whom will need to make critical decisions on whether or not to undergo local therapy, such as surgery or radiation, and on whether or not to have additional treatment after local therapy. Because the side effects of surgery and local radiation therapy can be serious, a need exists for a reliable test to determine the likelihood of progression. There is also a need for a reliable test to determine the likelihood of

recurrence after local treatment, because hormonal therapy and chemotherapy have significant side effects as well. We are in the process of defining our prostate cancer gene panel and we have completed initial feasibility studies and gained access to clinical samples correlated with outcome data in prostate cancer under a collaborative agreement with an academic group.

Renal Cell Cancer Recurrence and Response Test

We are in the early development phase for a test to predict the likelihood of recurrence and response to therapy in renal cell cancer. Approximately 40,000 individuals were expected to be diagnosed with renal cell cancer in the United States in 2006. Recently reported studies suggest that some of these patients may respond to new treatments.

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We have completed initial feasibility studies to extract RNA from renal cell cancer specimens and are currently working to define potential products for patients with renal cell cancer under a collaborative agreement with an academic group that has access to clinical samples correlated to outcome data.

Non-small Cell Lung Cancer Recurrence and Response Test

We are in the early development phase for a test to predict the likelihood of chemotherapy benefit in early stage, non-small cell lung cancer. Approximately 160,000 individuals were expected to be diagnosed with non-small cell lung cancer in the United States in 2006, of which approximately 45,000 of those patients were expected to be diagnosed before the cancer spreads and will need to make chemotherapy treatment decisions. Recent clinical studies suggest that at least some of those early stage patients will benefit from chemotherapy. The use of chemotherapy in early stage non-small cell lung cancer is relatively recent and is likely to accelerate. We have completed initial feasibility studies in lung tissues as a part of our EGFR inhibitor program described below and are in the process of defining our lung cancer gene panel. We have a collaborative agreement with an academic group that has access to clinical samples correlated to outcome data.

Melanoma Recurrence and Response Test

We are in the early development phase for a test to predict the likelihood of recurrence and response to therapy for patients with melanoma. Approximately 70,000 individuals were expected to be diagnosed with melanoma in the United States in 2006, of which approximately 60,000 of those patients were expected to be diagnosed before the cancer spreads and will need to make chemotherapy decisions. Recently reported studies suggest that some of these patients may respond to new treatments. We have conducted initial feasibility studies to extract RNA from melanoma cancer specimens and are currently working to define potential products for melanoma under a collaborative agreement with an academic group that has access to tissue samples that have been correlated to outcome data.

Product Development Opportunities for Targeted Therapeutics

Both anti-cancer drugs recently approved by 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 our individualized 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. We have completed several studies with different companies to evaluate our technology, and we have discussed our clinical development platform with pharmaceutical companies for exploratory clinical studies.

Epidermal Growth Factor Receptor, or EGFR, Inhibitor Response Test

We are in the early development phase to develop tests to predict the likelihood of response to the EGFR inhibitor class of drugs. The market opportunity for these tests will initially be limited to metastatic disease in lung and colon cancer, with an estimated 60,000 patients in the United States in 2006, where such drugs are currently approved. We have conducted three small clinical research studies in lung cancer, colon cancer and head and neck cancer which allowed us to identify and file patent applications on a number of genes which may predict the response to EGFR inhibitors. Further clinical development may require partnerships with pharmaceutical companies that have access to appropriate clinical trial specimens.

In July 2005, we signed 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 carcinoma.

Erbitux is a targeted therapy currently approved for the treatment of metastatic colorectal carcinoma. Consistent with terms we generally require in our collaborative agreements, the agreement provides for research funding support and milestone payments and provides us commercial rights to diagnostic tests that result from the collaboration.

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Targeted Therapies in Breast Cancer

We entered into collaborative agreements with Aventis, Inc., a member of the sanofi-aventis group, and the Eastern Cooperative Oncology Group to investigate the ability of gene expression in fixed-paraffin-embedded tissues to predict the likelihood of response to adjuvant chemotherapy, including Taxotere, in patients with early breast cancer and zero to three involved lymph nodes. The agreements provide us with commercial rights to diagnostic tests that may result from the collaboration and were effective as of December 1, 2005.

We cannot assure you that any of the above product opportunities or products in development will ever be commercialized or, if commercialized, will ever be successful.

Technology

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

Extract RNA from FPE-tumor Biopsies

Our product development requires that we be able to quantify the relative amounts of RNA in patients FPE tissue specimens. We have developed proprietary technology, intellectual property and know-how for optimized and automated methods for extraction and analysis of RNA from FPE tissue. Although others can extract RNA from FPE tissue, to our knowledge the process has not been optimized and scaled up for high-throughput clinical testing and large-scale clinical development studies involving large numbers of genes. Our process uses commercially available reagents and instruments with our own proprietary process and automation protocols, which results in RNA extraction from the range of tissues used in our clinical development studies and our commercial laboratory test.

Amplify and Detect Diminished Amounts of RNA Consistently

We use a well-established technology that we license from Roche called RT-PCR as the basis for our quantitative molecular pathology assays. This technology uses 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. Together with the inherent amplification of PCR, our platform provides us with sophisticated capabilities to quantify RNA levels from minimal amounts of 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. Human tissues contain thousands of different genes that are often highly related in sequence content, making it challenging for genomic tests to specifically identify molecules of interest. Our RT-PCR platform is highly specific because it works only when three different test reagents, called DNA probes and primers, independently match each gene 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. Our technology is also capable of quantifying non-coding RNA sequences that are present in miniscule quantities within tissues. The ability to utilize these sequences allows us to design highly specific assays for closely related genes.

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 laboratory to produce consistently precise and accurate gene expression results. Our quality control methods for our reagents and processes, along with

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our software for automation, sample tracking, data quality control and statistical analysis, add to the reproducibility and precision of our test.

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

Analyze Hundreds of Genes

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

Employ Advanced Information Technology

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

Competition

We believe that we compete primarily on the basis of:

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

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

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

our ability to screen hundreds of genes at a time;

the speed with which our clinical development platform can commercialize products;

our clinical collaborations with clinical study groups;

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.

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

introduced. We believe that our continued success depends on our ability to:

- continue to innovate and maintain scientifically advanced technology;
- enhance Onco*type* DX for breast cancer to provide information in response to additional indications;
- continue to validate our products, especially with respect to chemotherapy benefit;
- continue to obtain positive reimbursement decisions from payors;
- expand Onco*type* DX for use in other forms of cancer;

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attract and retain skilled scientific and sales personnel;

obtain patents or other protection for our products;

obtain and maintain our clinical laboratory accreditations and licenses; and

successfully market and sell Onco*type* DX.

Currently, our principal competition comes from existing diagnostic methods utilized by pathologists and oncologists, which generally involve assessing and evaluating the grade and stage of cancerous tumors when determining risk of recurrence. These methods, which have been used for many years and are therefore difficult to change or supplement, are typically accomplished in a short period of time without much expense. In addition, companies offering capital equipment and inexpensive kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which facilitates adoption more readily than tests like Onco*type* DX that are performed outside the pathology laboratory. Also, few diagnostic methods are as expensive as Onco*type* DX and others may develop lower-priced, less complex tests that could be viewed as the equivalent of ours.

We also face competition from many companies that offer products or have conducted research to profile gene expression in breast cancer, including Agendia B.V. and AviaraDX. Commercial laboratories with strong distribution networks for diagnostic tests, such as Genzyme Corporation, Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, may become competitors. Other potential competitors include companies that develop diagnostic tests such as Bayer Healthcare LLC, Celera Genomics, a division of Applera Corporation, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd, and Veridex LLC, a Johnson & Johnson company, other small companies and academic and research institutions. In addition, in December 2005, the federal government allocated a significant amount of funding to The Cancer Genome Atlas, a project aimed at developing a comprehensive catalog of the genetic mutations and other genomic changes that occur in cancers and maintaining the information in a free public database. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and these products may compete with ours.

Our test is currently considered relatively expensive for a diagnostic test, and we expect to raise prices in the future. Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that could be viewed by physicians and payors as functionally equivalent to our test. Some competitors have developed tests cleared for marketing by FDA, and there may be a marketing differentiation or a perception that an FDA-cleared test is more desirable than Onco*type* DX. Competition among these entities to recruit and retain highly qualified scientific, technical and professional personnel and consultants is also intense. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our test, which could prevent us from increasing or sustaining our revenues, or achieving or sustaining profitability.

Reimbursement

Revenues for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid, patients and in some cases, from hospitals or referring laboratories (who, in turn bill third-party payors for testing).

To gain broad reimbursement coverage, we are focusing on educating payors on the following Onco*type* DX attributes:

Test Performance. Onco*type* DX provides results that have been documented in clinical studies to be reproducible, sensitive, accurate and specific to the patient s tumor. Patients may benefit from treatment decisions based on prediction of the likelihood of recurrence, survival and chemotherapy benefit.

Clinical Utility. Patients are provided a Recurrence Score on a risk continuum that may contribute to decision making regarding the use of adjuvant chemotherapy. We believe the large difference in risk of

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distant recurrence between tumors with low Recurrence Scores and high Recurrence Scores is indicative of the clinical utility of our test.

Peer-reviewed Publication and Consistent Study Outcomes. The 2003 NSABP validation study was peer-reviewed and published in *The New England Journal of Medicine* in December 2004. In May 2006, two peer-reviewed articles were published supporting the clinical validity of Onco*type* DX and, therefore, the use and coverage of Onco*type* DX. *The Journal of Cancer Oncology* published the results of the 2004 NSABP study supporting the predictive value of Onco*type* DX on the likelihood of chemotherapy benefit. *Breast Cancer Research* published the results of the Kaiser Permanente study showing a significant correlation between the Onco*type* DX recurrence score and breast cancer survival. Physicians and payors often require one, and many require two or more, peer-reviewed publications to provide a basis for use and reimbursement decisions. The results of the independent Kaiser Permanente study reinforce the findings in the NSABP study. We believe that additional publications, including our findings on the magnitude of chemotherapy benefit, will increase usage and create a more favorable reimbursement environment.

Patient and Physician Demand. Increasing awareness and demand in the cancer community for Onco*type* DX will be necessary for widespread payor adoption. Increased usage of the test by physicians can influence payors and facilitate the reimbursement decision process.

Improved Economics. We are sponsoring third-party studies and providing information to payors to demonstrate the economic benefits that can result from the use of Onco*type* DX. A health economic analysis of Onco*type* DX was published in *The American Journal of Managed Care* in May 2005.

As a relatively new test, Onco*type* DX may be considered investigational by payors and not covered under their reimbursement policies. Consequently, we have pursued case-by-case reimbursement and expect the 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 Onco*type* DX based upon clinical evidence showing the utility of the test. As of February 2007, health plans covering nearly 100 million lives have approved our test for coverage.

As of December 31, 2006, Aetna, Inc., Kaiser Foundation Health Plan, Inc. and National Heritage Insurance Company, or NHIC, the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, had issued positive coverage determinations for Onco*type* DX. In January 2007, United HealthCare Insurance Company entered into a national laboratory services agreement to support reimbursement for our test. In addition, many regional payors have issued policies supporting reimbursement for our test. These regional payors include Harvard Pilgrim Health Care, Inc., Medical Mutual of Ohio, Humana, Healthnet, Premera Blue Cross, Blue Cross/Blue Shield of Alabama, Blue Cross/Blue Shield of Minnesota, Blue Cross/Blue Shield of South Carolina, Mountain State Blue Cross, covering West Virginia, and CareFirst, covering Blue Cross of Delaware, Maryland and District of Columbia. The Federal Employees Health Benefits Program has also made a positive coverage determination for beneficiaries who are covered under their Blue Cross/Blue Shield plan option. Where policies are not in place, we pursue case-by-case reimbursement. Through this process, as of December 31, 2006, more than 500 health insurance companies, third-party administrators, provider networks and other health systems had reimbursed one or more Onco*type* DX tests. We believe that it may take several years to achieve successful reimbursement with a majority of payors. However, we cannot predict whether, or under what circumstances, payors will reimburse for our tests. Payment amounts can also vary across individual policies and coverage and payment policies, when adopted, are generally applied prospectively rather than retroactively. Denial of coverage by payors, or payment at inadequate levels, would have a material adverse impact on market acceptance of our products.

In early 2005, the Medical Advisory Panel of the Blue Cross and Blue Shield Association s Technology Evaluation Center, or BCBSA, a technology assessment group, concluded that the existing clinical data in support of Onco*type* DX does not meet the panel s technology criteria for clinical effectiveness and appropriateness. This assessment is provided for informational purposes to members of BCBSA and can be used by third-party payors and health care providers such as Blue Cross and Blue Shield, which provide healthcare coverage for nearly one-third of all Americans, as grounds to deny coverage for Onco*type* DX. Other payors have determined that the test is investigational or have issued negative technology assessment reviews.

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

Medicare and Medicaid. In determining whether or not Medicare will pay for a test, the Centers for Medicare and Medicaid Services, or CMS, which oversees Medicare, can permit the contractors, who process and pay Medicare claims, to make that determination or it can make a national coverage determination, which will bind all Medicare contractors. To date, CMS has not issued a national coverage determination on Onco*type* DX. As a result, whether or not Medicare will cover the test when billed by us is the decision of NHIC, the current local Medicare carrier for California and the contractor with jurisdiction to process claims submitted by us. In January 2006, NHIC released a local coverage determination providing coverage for the Onco*type* DX test for female patients with estrogen-receptor positive, node-negative carcinoma of the breast when the ordering physician has determined, prior to ordering the test, that the intention to treat or not treat with adjuvant chemotherapy would be contingent, at least in part, on the results of the test for the individual patient in question. The local coverage determination was based upon a determination by NHIC that the Onco*type* DX test is safe and effective and reasonable and necessary to contribute to breast cancer diagnosis and major treatment decisions. The local coverage determination indicated that case-by-case review may be performed, as needed, and the test will be covered only when ordered by the treating physician, when necessary for diagnosis or treatment decisions and when used in patient care. The local coverage determination states that the Onco*type* DX test will be covered only when performed within six months of diagnosis of breast cancer and that the test will not be covered for male patients with breast cancer or for patients with recurrent or metastatic breast cancer who have had a previous Onco*type* DX test. The local coverage determination is effective for Onco*type* DX tests provided on or after February 27, 2006.

The local coverage determination explains that most or all coverage decisions for Medicare beneficiaries related to the Onco*type* DX tests will be made by NHIC. Until recently, there had been some question as to whether claims for Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue samples were obtained may be billed by us to NHIC or must be incorporated in the payment that the hospital receives for their services related to the patient s breast cancer. As of December 31, 2006, the volume of patients who fell into this category represented a very small portion (approximately 2%) of our total testing population.

Based on a final rule effective January 1, 2007, we are permitted to submit claims to NHIC for the Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients or outpatients at the time the tumor tissue samples were obtained, but only if the test was ordered at least 14 days following the date of the patient s discharge from the hospital and where other specified conditions are met. We are in the process of making arrangements with hospitals for payment of the test when performed for the small portion of Medicare beneficiaries, representing approximately 3% of our total testing population, who are hospital inpatients or outpatients at the time specimens are collected and who do not meet criteria under the final rule for billing by us. Finally, we have been engaged in discussions with the Centers for Medicare/Medicaid Services, or CMS, about the application of the final rule to hospital outpatients. We believe the final rule should not apply to the Onco*type* DX tests performed on tumor tissue samples obtained while the patient is a hospital outpatient, and that the tests performed on tissue samples taken from hospital outpatients are

eligible to be billed by us under the Medicare program, regardless of when the testing of such tissue samples takes place. While we are continuing to pursue this matter, at this point, CMS intends for the final rule to apply to outpatients as well as inpatients, and we are notifying hospitals accordingly.

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In addition, each state Medicaid program, which pays for services furnished to the eligible medically indigent, will usually make its own decision whether or not to cover Onco*type* DX. To date, we have a limited number of approvals from state Medicaid programs.

Medicare currently contracts with a large number of fiscal intermediaries and carriers that are responsible for processing and paying claims. Within the next few years, Medicare is expected to reduce this number to fifteen regional Medical Administrative Contractors, or MACs. If NHIC is not selected as one of these regional MACs, we cannot be certain that we will obtain a positive local coverage determination from another contractor.

Payment

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

At the present time, there is no specific Current Procedural Terminology (CPT) procedure code to report Onco*type* DX. Therefore, the test generally must be reported under a non-specific, unlisted procedure code, which is subject to manual review of each claim. We have been informed by NHIC that, under the local coverage determination, we may expect claims to be paid consistent with the average allowed reimbursement rate for Onco*type* DX claims that were billed and processed to completion as of September 30, 2005.

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

Several provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA, may affect future payments for clinical laboratory testing services, including Onco*type* DX. First, the Clinical Laboratory Fee Schedule payments under Medicare are frozen through 2008 with zero-percent annual adjustment. This would affect Medicare and Medicaid payments for Onco*type* DX if a specific procedure code and Clinical Laboratory Fee Schedule payment are assigned to the test. Second, Congress authorized the Medicare program to conduct a demonstration project on applying competitive bidding to certain clinical laboratory tests. It is not clear whether competitive bidding will be applied more broadly to clinical laboratory services under Medicare at some point in the future and, if so, whether this would impact payment for Onco*type* DX, which is provided solely by us. Third, Medicare is reforming the local contractor process to replace current contracts with fiscal intermediaries, who are billed by hospitals and other institutional providers, and carriers, which are billed by physicians, independent laboratories and other suppliers, with new contracts. These reforms may result in a change in the contractors to whom

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

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Regulation

Clinical Laboratory Improvement Amendments of 1988

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

We have a certificate of accreditation under CLIA to perform testing and are accredited by CAP. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. The standards applicable to the testing which we perform may change over time. We cannot assure you that we will be able to operate profitably should regulatory compliance requirements become substantially more costly in the future.

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

Food and Drug Administration

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

Clinical laboratory services are not typically subject to FDA regulation, but in vitro diagnostic test kits and reagents and equipment used by these laboratories may be subject to FDA regulation. Clinical laboratory tests that are developed and validated by a laboratory for use in examinations the laboratory performs itself are called laboratory development tests, or LDTs. Most LDTs currently are not subject to pre-market review by FDA although analyte-specific reagents or software provided to clinical laboratories by third parties and used by clinical laboratories to perform LDTs may be subject to review by FDA prior to marketing. We believe that Onco*type* DX is a type of LDT. We believe that Onco*type* DX is not subject to regulation under current FDA policies and have communicated this conclusion to FDA staff. We believe that the container we provide for collection and transport of tumor samples from a pathology laboratory to our laboratory is a medical device subject to FDA regulation but exempt from pre-market review.

In January 2006, we received a letter from FDA regarding Onco*type* DX inviting us to meet with FDA to discuss the nature and appropriate regulatory status of and the least burdensome ways that we may fulfill any FDA pre-market review requirements that may apply. In September 2006, FDA issued draft guidance on a new class of tests called In Vitro Diagnostic Multivariate Index Assays. This draft guidance, which is intended for public comment, represents the first public discussion surrounding FDA s position regarding the regulation of certain laboratory-developed tests. Under this draft guidance, Onco*type* DX could be classified as either a Class II or a Class III medical device, which may require varying levels of FDA pre-market review depending upon intended use and on the level of control

necessary to assure the safety and effectiveness of the test. FDA held a public meeting on February 8, 2007 at which a number of interested parties commented on the draft guidance. The draft guidance was open for public comment until March 5, 2007.

We submitted formal comments in response to the draft guidance and we intend to continue our ongoing dialogue with FDA with respect to the regulatory status of the Onco*type* DX breast cancer tests. We have presented information regarding Onco*type* DX to FDA and continue to believe that our tests are appropriately regulated under

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CLIA and should not require pre-market review by FDA. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for Onco*type* DX, either through new enforcement policies adopted by FDA or new legislation enacted by Congress. If pre-market review is required, our business could be negatively impacted until such review is completed and approval or clearance to market is obtained, and FDA could require that we stop selling our test pending pre-market approval. If our test is allowed to remain on the market but there is uncertainty about our test or if it is labeled investigational by FDA, 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 FDA. If pre-market review is required by FDA, there can be no assurance that our test will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, subject us to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Notwithstanding the above, we may decide to voluntarily pursue FDA pre-market approval of Onco*type* DX if we determine that doing so would be appropriate. Pursuing voluntary market review may, for example, facilitate third-party payor coverage for Onco*type* DX test or serve to differentiate claims about the intended use of Onco*type* DX from those of other tests.

Should any of the reagents obtained by us from vendors and used in conducting our LDT be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing 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, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by health care providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

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

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

Federal and State Self-referral Prohibitions

We are subject to the federal 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 of $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 can not be certain that regulators would find these arrangements to be in compliance with Stark, PORA or similar state

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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;
- exclusion from federal healthcare programs, including the Medicare and Medicaid programs; and
- a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law s prohibition.

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

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

Federal and State Anti-kickback Laws

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 the 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 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. California s anti-kickback statute, commonly referred to as Section 650, has been interpreted by the California Attorney General and California courts in substantially the same way as the 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.

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.

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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 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 applies to discounts provided by providers and suppliers, including laboratories, to clients with respect to Medicare, Medicaid, private pay or HMO patients, where the referring physician or institution bills the payor for the test, not when the service provider 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.

California does not have a discount safe harbor. However, certain licensees, such as hospitals or physicians, may only mark-up laboratory tests purchased by those licensees from a laboratory if certain disclosures are made to patients and third-party payors regarding the mark-up. Therefore, if and when we elect to offer discounts to California customers, including any hospital or physician, such discounts would not likely be viewed by regulators as prohibited under Section 650 because the mark-up would be disclosed by the customer to its buyer under California s mark-up laws. In contrast, any such discounts provided by us to our non-California customers would have to be analyzed under California s Section 650.

The personal services safe harbor to the Anti-kickback Law provides that remuneration paid to a referral source for personal services will not violate the Anti-kickback Law provided all of the elements of that safe harbor are met. One element is that, if the agreement is intended to provide for the services of the physician on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals. Our personal services arrangements with some physicians did not meet the specific requirement of this safe harbor that the agreement specify exactly the schedule of the intervals of time to be spent on the services because the nature of the services, for example, speaking engagements, does not lend itself to exact scheduling and therefore meeting this element of the personal services safe harbor is impractical. Failure to meet the terms of the safe harbor does not render an arrangement illegal. Rather, an arrangement would not have the protections of the safe harbor if challenged by a regulator and, if necessary, the parties might be required to demonstrate why the arrangement does not violate the Anti-kickback Law.

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 Fraud and Abuse Laws

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

Further, the Federal False Claims Act prohibits a person from knowingly submitting a claim or making a false record or statement in order to secure payment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having

knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government s involvement, then the plaintiff will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid.

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California Laboratory Licensing

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

If our 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 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 laboratory is required to be licensed by New York. We maintain such licensure for our laboratory under New York state laws and regulations, which establish standards for:

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

physical requirements of a facility;

equipment; and

quality control.

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

Patents and Proprietary Technology

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patent applications, copyrights, trademarks, trade secret laws and confidentiality, material data transfer agreements, licenses and invention assignment agreements to protect our intellectual property rights. We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We generally protect this information with reasonable security measures.

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As December 31, 2006, we had two issued patents, one of which was issued jointly to us and to the NSABP, and a number of pending U.S. patent applications, including provisional and non-provisional filings. Our issued patents expire in 2023 and 2024, respectively. Some of these U.S. patent applications also have corresponding pending applications under the Patent Cooperation Treaty in Canada, Europe, Japan and Australia. In these patent applications, we have either sole or joint ownership positions. In those cases where joint ownership positions were created, we have negotiated contractual provisions providing us with the opportunity to acquire exclusive rights under the patent applications. Under three patent applications, we have elected to allow exclusive options to lapse without exercising the option. The joint ownership agreements generally are in the form of material data transfer agreements that were executed at the onset of our collaborations with third parties.

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

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

An adverse determination in litigation or interference proceedings to which we may become a party relating to any patents issued to us in the future or any patents owned by third parties could subject us to significant liabilities to third parties or require us to seek licenses from third parties. Furthermore, if we are found to willfully infringe these patents, we could, in addition to other penalties, be required to pay treble damages. Although patent and intellectual property disputes in this area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory or commercially feasible terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign Onco*type* DX or other of our tests to avoid infringement, or such redesign may take considerable time, and force us to reassess our business plans. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling Onco*type* DX or other of our tests, which would have a significant adverse impact on our business.

All employees and technical consultants working for us are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. Confidentiality agreements provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. 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 have obtained from Roche Molecular Systems, Inc. a non-exclusive license under a number of U.S. patents claiming nucleic acid amplification processes known as polymerase chain reaction, or PCR, homogeneous polymerase chain reaction, and reverse transcription polymerase chain reaction, or RT-PCR. We use these processes in our research and development and in the processing of our tests. The Roche license is limited to the performance of clinical laboratory services within the United States and Puerto Rico, and does not include the right to make or

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sell products using the patented processes. The license continues as long as the underlying patent rights are in effect, but is subject to early termination by Roche under the following circumstances:

- a change in our ownership;
- a declaration of bankruptcy or insolvency, the making of an assignment for the benefit of our creditors, having a receiver appointed, or losing the federal or state licenses necessary for our operation;
- a change in our status to a non-profit entity or government institution; or
- our breach of or default under a material term of the license.

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

Oxford Finance Agreements

We have entered into a master security agreement and a number of promissory notes with Oxford Finance Corporation to finance equipment leases, computer and software leases and leasehold improvements. Under the master security agreement, we granted a security interest to Oxford in all of our goods, equipment, instruments and investment property. Events that would constitute a default by us under the master security agreement include, among others, our failure to pay an obligation when due, an attempt by us to sell, lease, transfer or encumber the collateral, our failure to maintain liability insurance as required by the agreement; our dissolving, becoming insolvent, filing for bankruptcy or having a receiver appointed, a change in our ownership or a material adverse change in our financial condition, business or operations.

If we default under the master security agreement, Oxford may declare all of our indebtedness under the promissory notes to be immediately due and payable.

The promissory notes provide that amounts borrowed will be repaid in periodic installments. Principal underlying promissory notes to finance equipment leases must be paid in 45 to 48 monthly installments, and principal underlying promissory notes to finance computer and software leases and leasehold improvements must be paid in 36 monthly installments. Prepayment of indebtedness under a promissory note is subject to a prepayment penalty and is allowed only after the first anniversary of the note. As of December 31, 2006, the outstanding principal amount under these promissory notes was $7.3 million.

Research and Development Expenses

Research and development expenses were $12.8 million, $9.5 million and $10.0 million for the years ended December 31, 2006, 2005 and 2004, respectively.

Employees

As of December 31, 2006, we had 191 employees. None of our employees are covered by collective bargaining arrangements, and our management considers its relationships with employees to be good.

Available Information

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.

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

RISKS RELATED TO OUR COMPANY

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

We have incurred substantial net losses since our inception. For the year ended December 31, 2006, we incurred a net loss of $28.9 million. From our inception in August 2000 through December 31, 2006, we had an accumulated deficit of approximately $125.1 million. To date, we have not, and we may never, achieve revenues sufficient to offset expenses. We expect to devote substantially all of our resources to continue commercializing our existing test, Onco*type* DX, and to develop future tests.

We expect to incur additional losses in future years, and we may never achieve profitability. In addition, we have only recently begun to commercialize Onco*type* DX and do not expect our losses to be substantially mitigated by revenues from Onco*type* DX or future products, if any, for a number of years.

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

In recent years, we have incurred significant costs in connection with the development of Onco*type* DX. Our research and development expenses were $12.8 million for the year ended December 31, 2006. We expect our research and development expense levels to remain high for the foreseeable future as we seek to enhance our existing test and develop new tests. As a result, we will need to generate significant revenues in order to achieve profitability. Our failure to achieve profitability in the future could cause the market price of our common stock to decline.

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

Oncotype DX has a list price of $3,460. Physicians and patients may decide not to order Onco*type* DX unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid, pay a substantial portion of the test s price. There is significant uncertainty concerning third-party reimbursement of any test incorporating new technology, including Onco*type* DX. 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, and

supported by peer-reviewed publications.

Since each payor makes its own decision as to whether to establish a policy to reimburse, seeking these approvals is a time-consuming and costly process. To date, we have secured policy-level reimbursement approval from only a limited number of third-party payors and have a limited number of approvals for state Medicaid programs. We cannot

be certain that coverage for Onco*type* DX will be provided in the future by any third-party payors.

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 such as Blue Cross and Blue Shield, which provide healthcare coverage for nearly one-third of all Americans, as grounds to deny coverage for a test or procedure. Onco*type* DX has received negative assessments and may receive additional negative assessments in the future. For example, in early 2005, the Medical Advisory Panel of the Blue Cross and Blue Shield Association s Technology Evaluation Center, a technology

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assessment group, concluded that the existing clinical data in support of Onco*type* DX did not meet the panel s technology criteria for clinical effectiveness and appropriateness.

In January 2006, NHIC, the California Medicare contractor with responsibility for processing and paying claims submitted by us, released a local coverage determination providing coverage for Onco*type* DX when used in accordance with the terms of the determination. The local coverage determination is effective for Onco*type* DX tests provided on or after February 27, 2006. Until recently, there had been some question as to whether claims for Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue samples were obtained may be billed by us to NHIC or must be incorporated in the payment that the hospital receives for their services related to the patient s breast cancer. As of December 31, 2006, the volume of patients who fell into this category represented a very small portion (approximately 2%) of our total testing population.

Based on a final rule effective January 1, 2007, we are permitted to submit claims to NHIC for the Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients or outpatients at the time the tumor tissue samples were obtained, but only if the test was ordered at least 14 days following the date of the patient s discharge from the hospital and where other specified conditions are met. We are in the process of making arrangements with hospitals for payment of the test when performed for the small portion of Medicare beneficiaries, representing approximately 3% of our total testing population, who are hospital inpatients or outpatients at the time specimens are collected and who do not meet criteria under the final rule for billing by us. Finally, we have been engaged in discussions with the Centers for Medicare/Medicaid Services, or CMS, about the application of the final rule to hospital outpatients. We believe the final rule should not apply to the Onco*type* DX tests performed on tumor tissue samples obtained while the patient is a hospital outpatient, and that the tests performed on tissue samples taken from hospital outpatients are reimbursable under the Medicare program, regardless of when the testing of such tissue samples takes place. While we are continuing to pursue this matter, at this point, CMS intends for the final rule to apply to outpatients as well as inpatients, and we are notifying hospitals accordingly.

Insurers, including managed care organizations as well as government payors such as Medicare, have increased their efforts to control the cost, utilization and delivery of health care services. From time to time, Congress has considered and implemented changes in the Medicare fee schedules in conjunction with budgetary legislation, most recently in February 2006. Further reductions of reimbursement for Medicare services may be implemented from time to time. Reductions in the reimbursement rates of other third- party payors have occurred and may occur in the future. These measures have resulted in reduced prices, added costs and decreased test utilization for the clinical laboratory industry.

Medicare currently contracts with a large number of fiscal intermediaries and carriers that are responsible for processing and paying claims. Within the next few years, Medicare is expected to reduce this number to fifteen regional Medical Administrative Contractors, or MACs. If NHIC is not selected as one of these regional MACs, we cannot be certain that we will obtain a positive local coverage determination from another contractor.

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

If the U.S. Food and Drug Administration, or FDA, were to begin regulating our test, we could be forced to stop sales of Oncotype DX, we could experience significant delays in commercializing any future products, we could incur substantial costs and time delays associated with meeting requirements for pre-market approval or we could experience decreased demand for or reimbursement of our test.

Clinical laboratory tests like Onco*type* DX are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as administered through the CMS, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called laboratory development tests, or LDTs. Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We believe that Onco*type* DX is not a diagnostic kit and also believe that it is an LDT. As a result, we believe Onco*type* DX should not be subject to

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regulation under established FDA policies. The container we provide for collection and transport of tumor samples from a pathology laboratory to our laboratory is a medical device subject to FDA regulation but is currently exempt from pre-market review by FDA.

In January 2006, we received a letter from FDA regarding Onco*type* DX inviting us to meet with FDA to discuss the nature and appropriate regulatory status of and the least burdensome ways that we may fulfill any FDA pre-market review requirements that may apply. In September 2006, FDA issued draft guidance on a new class of tests called In Vitro Diagnostic Multivariate Index Assays. This draft guidance, which is intended for public comment, represents the first public discussion surrounding FDA s position regarding the regulation of certain laboratory-developed tests. Under this draft guidance, Onco*type* DX could be classified as either a Class II or a Class III medical device, which may require varying levels of FDA pre-market review depending upon intended use and on the level of control necessary to assure the safety and effectiveness of the test. The draft guidance was open for public comment until March 5, 2007, during which time we and others had the opportunity to comment on their proposed guidelines. In addition, FDA held a public meeting on February 8, 2007 at which several interested parties commented on the draft guidance.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for Onco*type* DX, either through new enforcement policies adopted by FDA or new legislation enacted by Congress. If pre-market review is required, our business could be negatively impacted until such review is completed and approval or clearance to market is obtained, and FDA could require that we stop selling our test pending pre-market approval. If our test is allowed to remain on the market but there is uncertainty about our test or if it is labeled investigational by FDA, 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 FDA. If pre-market review is required by FDA, there can be no assurance that our test will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Notwithstanding the above, we may decide voluntarily to pursue FDA pre-market review of Onco*type* DX if we determine that doing so would be appropriate.

Should any of the reagents obtained by us from vendors and used in conducting our LDT be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing 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 marketing our test, those trials could lead to delays or failure to obtain necessary regulatory approvals and harm our ability to become profitable.

If FDA decides to regulate our test, it may require extensive pre-market clinical testing prior to submitting a regulatory application for commercial sales. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory 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

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approval for our test. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our test, or to become profitable.

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

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

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

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

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

Medicare billing and payment regulations applicable to clinical laboratories;

the federal Medicare and Medicaid Anti-kickback Law and state anti-kickback prohibitions;

the federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;

the federal Health Insurance Portability and Accountability Act of 1996;

the Medicare civil money penalty and exclusion requirements; and

the federal civil and criminal False Claims Act.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

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

For the foreseeable future, we expect to derive substantially all of our revenues from sales of one test, Onco*type* DX. We have been selling this test since January 2004. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing test. We do not currently expect to commercialize tests for colon cancer until 2009, and we are not currently able to estimate when we may be able to commercialize tests for other cancers or whether we will be successful in doing so. If we are unable to increase sales of Onco*type* DX or to successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve profitability would be impaired, and the market price of our common stock could decline.

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

If medical practitioners do not order Onco*type* DX or any future tests developed by us, we will likely not be able to create demand for our products in sufficient volume for us to become profitable. To generate demand, we will need to continue to make oncologists, surgeons and pathologists aware of the benefits of Onco*type* DX and any products we may develop in the future through published papers, presentations at scientific conferences and one-on-one education by our sales force. In addition, we will need to demonstrate our ability to obtain adequate reimbursement coverage from third-party payors.

Existing guidelines and practices regarding the treatment of breast cancer recommend that chemotherapy be considered in most cases, including many cases in which our test may indicate that, based on our clinical trial results, chemotherapy is of little or no benefit. Accordingly, physicians may be reluctant to order a test that may suggest recommending against chemotherapy in treating breast cancer where current guidelines recommend consideration of such treatment. 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 order or support our test. These facts may make it difficult for us to convince medical practitioners to order Onco*type* DX for their patients, which could limit our ability to generate revenues and our ability to achieve profitability.

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

Some patients may decide not to order our test due to its list price of $3,460, part or all of which may be payable directly by the patient if the applicable payor denies reimbursement in full or in part. Even if medical practitioners recommend that their patients use our test, patients may still decide not to use Onco*type* DX, either because they do not want to be made aware of the likelihood of recurrence or they wish to pursue a particular course of therapy regardless of test results. If only a small portion of the patient population decides to use our test, we will experience limits on our revenues and our ability to achieve profitability.

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

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

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

We license from third parties technology necessary to develop our products. For example, we license technology from Roche Molecular Systems, Inc. that we use to analyze genes for possible inclusion in our tests and that we use in our

laboratory to conduct our test. In return for the use of a third party s technology, we may agree to pay the licensor royalties based on sales of our products. Royalties are a component of cost of product revenues and impact the margin on our test. We may need to license other technology to commercialize future products. Our business may suffer if these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary licenses on acceptable terms.

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Our competitive position depends on maintaining intellectual property protection.

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

As December 31, 2006, we had two issued patents, one of which was issued jointly to us and to the NSABP. Our pending patent applications may not result in issued patents, and we cannot assure you that our issued patent or any patents that might ultimately be issued by the U.S. Patent and Trademark Office will protect our technology. Any patents that may be issued to us might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

From time to time, the United States Supreme Court, other federal courts, U.S. Congress or the U.S. Patent and Trademark Office may change the standards of patentability and any such changes could have a negative impact on our business.

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

There are a number of patents and patent applications that may constitute prior art in the field of genomic-based diagnostics. We may be required to pay royalties, damages and costs to firms who own the rights to these patents, or we might be restricted from using any of the inventions claimed in those patents.

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

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

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We also face competition from many from companies that offer products or have conducted research to profile gene expression in breast cancer, including Agendia B.V. and AviaraDX. Commercial laboratories with strong distribution networks for diagnostic tests, such as Genzyme Corporation, Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, may become competitors. Other potential competitors include companies that develop diagnostic tests such as Bayer Healthcare LLC, Celera Genomics, a business segment of Applera Corporation, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd, and Veridex LLC, a Johnson & Johnson company, other small companies and academic and research institutions. Our competitors may invent and commercialize technology platforms that compete with ours. In addition, in December 2005, the federal government allocated a significant amount funding to The Cancer Genome Atlas, a project aimed at developing a comprehensive catalog of the genetic mutations and other genomic changes that occur in cancers and maintaining the information in a free public database. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and these products may compete with ours.

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

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

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

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

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

In the past, we have entered into clinical trial collaborations with highly regarded organizations in the cancer field, including the National Surgical Adjuvant Breast and Bowel Project, or NSABP, and Northern California Kaiser Permanente. 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

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collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for a test such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any product that may result from a collaboration.

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

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

We have multiple tests in various stages of development and devote considerable resources to research and development. For example, we are currently in the development stage of the application of our technology to predict recurrence and the therapeutic benefit of chemotherapy in colon cancer, and we are conducting early development studies in N+ prostate, renal cell and lung cancers and melanoma. Our N+ breast cancer program is being considered for a move to the validation phase with Onco*type* DX during 2007. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of other cancers, such as colon and those cancers, with the sensitivity and specificity necessary to be clinically and commercially useful for the treatment of other cancers, or that we can develop those technologies at all. In addition, before we can develop diagnostic tests for new cancers and commercialize any new products, we will need to:

- conduct substantial research and development;
- conduct validation studies;
- expend significant funds; and
- develop and scale-up our laboratory processes.

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

- failure of the product at the research or development stage;
- difficulty in accessing archival tissue samples, especially tissue samples with known clinical results; or
- lack of clinical validation data to support the effectiveness of the product.

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

demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

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

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical to us as we continue to develop our technologies and testing processes and as we attempt to transition to a

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company with more than one commercialized product. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

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

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

We do not have redundant laboratory facilities. We perform all of our diagnostic testing in our laboratory located in Redwood City, California. Redwood City is situated on or 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 may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

In order to rely on a third party to perform our tests, we could only use another facility with established state licensure and CLIA accreditation under the scope of which Onco*type* DX could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing to adopt Onco*type* DX and comply with the required procedures, or that this laboratory would be willing to perform the tests for us on commercially reasonable terms. In order to establish a redundant 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. Additionally, any new clinical laboratory facility opened by us would be subject to certification under CLIA and licensed by several states, including California and New York, which can take a significant amount of time and result in delays in our ability to begin operations.

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

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments. We developed our commercialization strategy for Onco*type* DX based on existing healthcare policies. Changes in healthcare policy, such as the creation of broad limits for diagnostic products in general or requirements that Medicare patients pay for portions of tests or services received, could substantially interrupt the sales of Onco*type* DX, increase costs and divert management s attention. For example, in 1989, the

U.S. Congress passed federal self-referral prohibitions commonly known as the Stark Law, significantly restricting, regulating and changing laboratories relationships with physicians. We cannot predict what changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

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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 supplier no longer supplies that equipment.

We rely solely on Applied Biosystems, a division of Applera Corporation, to supply some of the laboratory equipment on which we perform our tests. We periodically forecast our needs for laboratory equipment and enter into standard purchase orders with Applied Biosystems based on these forecasts. We believe that there are relatively few equipment manufacturers other than Applied Biosystems that are currently capable of supplying the equipment necessary for Onco*type* DX. Even if we were to identify other suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from Applied Biosystems the quality and quantity of equipment we require for Onco*type* DX, we may need to reconfigure our test process, which would result in delays in commercialization or an interruption in sales. If any of these events occur, our business and operating results could be harmed. Additionally, if Applied Biosystems deems us to have become uncreditworthy, it has the right to require alternative payment terms from us, including payment in advance. We are also required to indemnify Applied Biosystems against any damages caused by any legal action or proceeding brought by a third party against Applied Biosystems for damages caused by our failure to obtain required approval with any regulatory agency.

We also rely on a 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 can not be certain that these strategies will be effective. If we should encounter delays or difficulties in securing these laboratory materials, delays in commercialization or an interruption in sales could occur.

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

We have limited experience in processing our test and even more limited experience in processing large volumes of tests. We recently completed the expansion of our clinical laboratory facilities and have ramped up our testing capacity. We have begun to implement increases in scale and related processing, customer service, billing and systems process improvements, and to expand our internal quality assurance program to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process 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. 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. Since we have limited experience handling large volumes of Onco*type* DX tests, there can be no assurance that we will be able to perform tests on a timely basis at a level consistent with demand. If we encounter difficulty meeting market demand for Onco*type* DX, our reputation could be harmed and our future prospects and our business could suffer.

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

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

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

The marketing, sale and use of our test could lead to the filing of product liability claims if someone were to allege that our test failed to perform as it was designed. We may also be subject to liability for errors in the information we provide to customers or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we believe that our existing product liability insurance is adequate, we cannot assure you that our insurance would fully protect us from the financial impact of defending against product liability claims. Any

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product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation, result in the recall of our products, or cause current collaborators to terminate existing agreements and potential collaborators to seek other partners, any of which could impact our results of operations.

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

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

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

International sales as a percentage of net revenues are expected to remain minimal in the near term as we focus our efforts on the sale of Onco*type* DX in the United States. We have established an exclusive distribution network to sell Onco*type* DX in Israel and may enter into other similar arrangements in other countries in the future. Over the long term, we intend to grow our business internationally, and to do so we will need to attract additional distributors to expand the territories in which we sell Onco*type* DX. Distributors may not commit the necessary resources to market and sell Onco*type* DX to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize long-term international revenue growth.

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

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

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. 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 inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new tests and technologies.

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

sustain commercialization of our initial test or enhancements to that test;

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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;

fund our clinical validation study activities;

expand our research and development activities;

acquire or license technologies; and

finance capital expenditures and our general and administrative expenses.

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

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

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

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

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

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

competing technological and market developments;

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

changes in regulatory policies or laws that affect our operations.

If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities.

We must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new 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, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 and other requirements has increased our costs and required additional management resources. We have upgraded our finance and accounting systems,

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

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

None.

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ITEM 2. ***Properties***.

At December 31, 2006, we occupied approximately 48,000 square feet of laboratory and office space. On January 3, 2007, we entered into a lease agreement for an additional 48,000 square feet of office space, which we intend to occupy in March 2007. We believe that these facilities are adequate to meet our business requirements for the near-term and that additional space, when needed, will be available on commercially reasonable terms.

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

We were not a party to any legal proceedings other than in the ordinary course of our business at December 31, 2006, or at the date of this report.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2006.

Executive Officers

The names of our executive officers and their ages as of March 1, 2007, are as follows:

Name	Age	Position
Randal W. Scott, Ph.D.	49	Chief Executive Officer and Chairman of the Board
Kimberly J. Popovits	48	President, Chief Operating Officer and Director
Joffre B. Baker, Ph.D.	59	Chief Scientific Officer
Steven Shak, M.D.	56	Chief Medical Officer
G. Bradley Cole	51	Executive Vice President, Chief Financial Officer and Secretary

Randal W. Scott, Ph.D., has served as our Chairman of the Board and Chief Executive Officer since our inception in August 2000 and served as 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 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 is a director of Nuvelo, Inc., a biotechnology company. Ms. Popovits holds a B.A. in Business from Michigan State University.

Joffre B. Baker, Ph.D., has served as our Chief Scientific Officer since December 2000. From March 1997 to October 2000, Dr. Baker served as the Vice President for Research Discovery at Genentech. From March 1993 to October

2000, Dr. Baker oversaw Research Discovery at Genentech, which includes 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.

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

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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.

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

PART II

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

(a) Our common stock is traded on the NASDAQ Global Market under the symbol GHDX and has been trading since our initial public offering on September 29, 2005. The following table sets forth the range of high and low sale prices for our common stock, based on the last daily sale, in each of the quarters since our stock began trading:

	2006			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Stock price high	$ 16.70	$ 11.77	$ 14.64	$ 23.89
Stock price low	$ 9.11	$ 9.92	$ 10.86	$ 13.79

	2005			
	First Quarter	Second Quarter	Third Quarter(1)	Fourth Quarter
Stock price high	n/a	n/a	$ 11.75	$ 11.69
Stock price low	n/a	n/a	$ 11.55	$ 8.81

(1) From September 29, 2005

According to the records of our transfer agent, we had 156 stockholders of record as of March 1, 2007.

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

(b) On September 28, 2005, a Registration Statement on Form S-1 (File No. 333-126626) relating to our initial public offering was declared effective by the SEC. The closing was on October 4, 2005 and the net offering proceeds to us

were approximately $53.5 million. Through December 31, 2006, $29.1 million of the net proceeds were used to build our commercial capabilities in selling and marketing related to Onco*type* DX, $15.3 million were used to fund research and development programs for Onco*type* DX and in other cancers, and $6.8 million were used to expand facilities and laboratory operations capacity and for information systems infrastructure and no funds were used for working capital and general corporate purposes. A portion of the net proceeds may also be used for working capital and general corporate purposes and to acquire or invest in complementary businesses, technologies, services or products. Pending use for these or other purposes, net proceeds have been invested in interest bearing, investment grade securities.

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Stock Performance Graph

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

Set forth below is a line graph showing the cumulative total stockholder return (change in stock price plus reinvested dividends) assuming the investment of $100 on September 29, 2005 (the day of our initial public offering) in each of our common stock, the NASDAQ Market Index and the NASDAQ Biotechnology Index for the period commencing on September 29, 2005 and ending on December 31, 2006. 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 AND NASDAQ BIOTECH INDEX

	September 29, 2005	December 31, 2005	December 31, 2006
Genomic Health, Inc.	$ 100.00	$ 77.53	$ 158.30
NASDAQ Market Index	$ 100.00	$ 102.81	$ 101.72
NASDAQ Biotechnology Index	$ 100.00	$ 102.67	$ 113.47

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

The following selected consolidated financial data should be read together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2006 and 2005 and the selected consolidated statements of operations data for each year ended December 31, 2006, 2005 and 2004 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2004, 2003 and 2002 and the selected consolidated statements of operations data for each year ended December 31, 2003 and 2002 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,				
	2006	2005	2004	2003	2002
	(In thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product revenues	$ 27,006	$ 4,823	$ 227	$	$
Contract revenues	2,168	379	100	125	
Total revenues	29,174	5,202	327	125	
Operating expenses(1):					
Cost of product revenues	9,908	6,249	1,828		
Research and development	12,841	9,465	10,040	9,069	7,053
Selling and marketing	24,625	15,348	9,856	2,805	754
General and administrative	12,765	6,485	3,869	3,686	3,753
Total operating expenses	60,139	37,547	25,593	15,560	11,560
Loss from operations	(30,965)	(32,345)	(25,266)	(15,435)	(11,560)
Interest and other income (expense), net	2,045	984	271	185	492
Net loss	$ (28,920)	$ (31,361)	$ (24,995)	$ (15,250)	$ (11,068)
Basic and diluted net loss per share	$ (1.18)	$ (4.15)	$ (13.82)	$ (12.43)	$ (11.95)
Shares used in computing basic and diluted net loss per share	24,508,845	7,557,106	1,808,022	1,226,444	925,814

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

	Year Ended December 31,				
	2006	2005	2004	2003	2002
	(In thousands)				
Cost of product revenues	$ 167	$ 53	$ 5	$	$
Research and development	821	323	42		
Selling and marketing	779	274	38		
General and administrative	1,137	426	106		
	$ 2,904	$ 1,076	$ 191	$	$

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

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	At December 31,				
	2006	2005	2004	2003	2002
	(In thousands)				
Consolidated Balance Sheets Data:					
Cash and cash equivalents	$ 14,926	$ 18,839	$ 38,275	$ 11,062	$ 25,318
Short-term investments	29,289	50,688			
Working capital	37,535	65,801	36,771	10,046	25,165
Total assets	58,024	75,799	41,538	13,096	27,376
Notes payable, short-term	2,547	1,052		161	163
Notes payable, long-term	4,726	2,621			150
Convertible preferred stock			103,212	51,064	51,073
Accumulated deficit	(125,103)	(96,183)	(64,822)	(39,827)	(24,577)
Total stockholders equity (deficit)	41,829	67,517	(64,154)	(39,547)	(24,502)

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

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 for this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

Business Overview

We are a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. Our first test, Onco*type* DX, is used for early stage breast cancer patients to predict the likelihood of cancer recurrence, the likelihood of patient survival and the likelihood of chemotherapy benefit. All tumor samples are sent to our laboratory in Redwood City, California for analysis. Upon generation and delivery of a Recurrence Score report to the physician, we generally bill third-party payors for Onco*type* DX. The list price of our test is $3,460.

We launched Onco*type* DX in January 2004 and initially made sales to a select number of physicians in a few markets in the United States through a small direct sales force. Late in 2004 and continuing into 2006, we experienced a significant increase in demand for Onco*type* DX. For the year ended December 31, 2006, more than 14,500 tests were delivered for use in treatment planning, compared to more than 7,000 and more than 500 tests delivered for the years ended December 31, 2005 and 2004, respectively. Since the commercial launch of Onco*type* DX more than 21,500 tests have been delivered for use in treatment planning by more than 5,000 physicians. We believe increased demand in 2005 resulted from the publication of our validation study in *The New England Journal of Medicine* and the presentation of our chemotherapy benefit study at the San Antonio Breast Cancer Symposium, both of which occurred in December 2004. We also experienced increased demand in 2006 following clinical presentations at major symposia in December 2005 and February 2006, as well as the May 2006 publication of two peer-reviewed articles supporting the use and reimbursement of Onco*type* DX. The expansion of our domestic field sales organization in July 2006 also increased demand for our test. 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 future appearances or presentations at medical conferences or publication of articles will have similar impact on demand for Onco*type* DX. Moreover, we believe that each year we may experience decreased demand for our test in the summer months of July and August, which may be attributed to physicians, surgeons and patients scheduling vacations during this time. As of December 31, 2006, our laboratory had the capacity to process up to 7,000 tests per fiscal quarter.

We believe the key factors that will drive broader adoption of Onco*type* DX will be acceptance by healthcare providers of its clinical benefits, demonstration of the cost-effectiveness of using our test, expanded reimbursement by third-party payors, expansion of our sales force and increased marketing efforts. Reimbursement of Onco*type* DX by third-party payors is essential to our commercial success. In general, clinical laboratory services, when covered, are paid under various methodologies, including prospective payment systems and fee schedules.

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Reimbursement from payors depends upon whether a test covered under the patient s policy and if payment practices for the test have been established. As a relatively new test, Onco*type* DX may be considered investigational by payors and not covered under current reimbursement policies. Until we reach agreement with a payor on contract terms or a payor establishes a policy for payment of Onco*type* DX, we recognize revenue on a cash basis.

Upon commercialization of Onco*type* DX, we began working with third-party payors to establish reimbursement coverage policies. As of December 31, 2006, Aetna, Inc., Kaiser Foundation Health Plan, Inc. and National Heritage Insurance Company (NHIC), the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, had issued positive coverage determinations for Onco*type* DX. In January 2007, United HealthCare Insurance Company entered into a national laboratory services agreement to supporting reimbursement for our test. In addition, many regional payors had issued policies supporting reimbursement for our test. Where contracts or policies are not in place, we pursue case-by-case reimbursement. We believe that as much as 20% of our future test volume may be derived from Medicare patients. We are working with many payors to establish policy-level reimbursement which, if in place, should allow us to recognize revenues upon completing our test and submitting an invoice. We do not expect to recognize the majority of revenues in this manner until late 2007, at the earliest.

In early February 2006, we obtained our first reimbursement coverage outside of the United States. Clalit Health Care, the largest government payor in Israel, covering 60% of the population, established a reimbursement coverage policy for Onco*type* DX for their patients. Onco*type* DX is currently offered for sale in Israel under a testing and services agreement with a third party. Tests ordered in Israel are processed in our Redwood City, California central reference laboratory.

Effective December 2005, we entered into collaborative agreements with Aventis, Inc., a member of the sanofi-aventis group, and the Eastern Cooperative Oncology Group to investigate the ability of gene expression in fixed-paraffin-embedded tissues to predict the likelihood of response to adjuvant chemotherapy, including Taxotere, in patients with early breast cancer and zero to three involved lymph nodes. The agreements provide Genomic Health with commercial rights to diagnostic tests that may result from the collaboration and were effective as of December 1, 2005. We began to recognize revenue under these agreements in the first quarter of 2006.

We are continuing to work on extending Onco*type* DX for breast cancer into N+ and ER- populations. During 2007, we may introduce single gene information for ER and PR genes into the Onco*type* DX patient report to provide better information for improved treatment decision making. Also during 2007, we plan to conduct further studies using Onco*type* DX in N+ patients which, if successful, could result in a product offering sometime in 2008.

In July 2005 we signed a collaborative agreement with National Surgical Adjuvant Breast and Bowel Project, or NSABP, to begin work in colon cancer using our clinical development platform. This is the same group with which we conducted our successful clinical validation studies in breast cancer which led to our development of Onco*type* DX. The agreement requires certain payments to be made by us during the research and development period. If the collaboration results in a commercial product, we will be required to make additional payments upon first commercial sale and during commercialization of the product. At the American Society of Clinical Oncology meeting in June 2006, a study conducted with the NSABP was presented demonstrating correlation between gene expression and colon cancer recurrence in patients with stage II and III colon cancer treated with surgery. These data support additional studies and development of an Onco*type* DX test for colon cancer. During 2006, we entered into additional agreements with NSABP and other academic institutions to further our clinical studies in colon cancer, including arrangements for a clinical validation study.

In July 2005 we signed a collaborative agreement with Bristol-Myers Squibb Company and ImClone Systems Incorporated to develop a genomic test to predict the likelihood of response to Erbitux in colorectal cancer. Erbitux is a targeted therapy currently approved for the treatment of metastatic colorectal cancer. The agreement provides for

research funding support and milestone payments and gives us commercial rights to diagnostic tests that may result from the collaboration.

In December 2006, we finalized a collaborative agreement to sponsor a research project to validate a pre-specified gene panel and algorithm that will be used to predict clinical outcomes for stage II colon cancer patients treated either with surgery alone or surgery plus chemotherapy. The agreement requires certain payments to be

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made by us during the research and development period. If the collaboration results in a commercial product, we will be required to make additional payments upon first commercial sale and during commercialization of the product.

We are continuing to conduct research and early development studies in a variety of cancers other than breast cancer and in January 2007 announced the decision to move our colon program for Stage I and Stage II cancer patients into full scale development.

Since our inception, we have generated significant net losses. As of December 31, 2006, we had an accumulated deficit of $125.1 million. We incurred net losses of $28.9 million, $31.4 million and $25.0 million for the years ended December 31, 2006, 2005, and 2004, respectively. We expect our net losses to continue for at least the next two years. We anticipate that a substantial portion of our capital resources and efforts over the next several years will be focused on research and development, both to develop additional tests for breast cancer and to develop tests for other cancers, to scale up our commercial organization, and for other general corporate purposes. Our financial results will be limited by a number of factors, including establishment of coverage policies by third-party insurers and government payors, our ability in the short term to collect from payors often requiring a case-by-case manual appeals process, and our ability to recognize revenues other than from cash collections on tests billed until such time as reimbursement policies or contracts are in effect. Until we receive routine reimbursement and are able to record revenues as tests are performed and reports delivered, we are likely to continue reporting net losses.

Financial Operations Overview

Revenues

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

Cost of Product Revenues

Cost of product revenues represents the cost of materials, direct labor, costs associated with processing tissue samples including histopathology, anatomical pathology, paraffin extraction, reverse transcription polymerase chain reaction, or RT-PCR, and quality control analyses, license fees and delivery charges necessary to render an individualized test result. Costs associated with performing our test are recorded as tests are processed. License fees are recorded at the time product revenues are recognized or in accordance with other contractual obligations. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

Research and Development Expenses

Research and development expenses represent costs incurred to develop our technology and to carry out our clinical studies to validate our multi-gene tests and include salaries and benefits, allocated overhead and facility occupancy costs, contract services and other outside costs, and costs to acquire in-process research and development projects and technologies that have no alternative future use. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies.

We charge all research and development expenses to operations as they are incurred. All potential future product programs outside of breast and colon cancer are in the early development phase. The expected time frame in which a

test for one of these other cancers can be brought to market is uncertain given the technical challenges and clinical variables that exist between different types of cancers.

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We do not record or maintain information regarding costs incurred in research and development on a program or project 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. We believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

As a result of the uncertainties discussed above, 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.

Selling and Marketing Expenses

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

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel related costs, legal costs, including intellectual property, accounting costs and other professional and administrative costs.

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

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

Revenue Recognition

Product revenues for our first product, Onco*type* DX, from the commercial launch in January 2004 through December 31, 2006, have largely been recognized on a cash basis because we have limited collection experience and a limited number of contracts. Beginning in the fourth quarter of 2005 and continuing through 2006, we recognized some product revenue from private payors on an accrual basis. For the year ended December 31, 2006, a portion of Medicare related product revenue was recognized on an accrual basis.

Our product revenues for tests performed are recognized when the following criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed

or determinable; and (4) collectibility is reasonably assured. Criterion (2) is satisfied we perform the test and generate and deliver a report to the physician. Determination of criteria (3) and (4) is based on management s judgments regarding the nature of the fee charged for products or services delivered and the collectibility of those fees. Product revenues where all criteria set forth above are not met are recognized on a cash basis when cash is received.

We generally bill third-party payors for Onco*type* DX upon generation and delivery of a Recurrence Score report to the physician. As such, we take assignment of benefits and the risk of collection with the third-party payor.

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We usually bill the patient directly for amounts owed after multiple requests for payment have been denied or only partially paid by the insurance carrier. As a relatively new test, Onco*type* DX may be considered investigational by payors and not covered under their reimbursement policies. Consequently, we pursue case-by-case reimbursement where policies are not in place or payment history has not been established.

In 2006 we began accruing an allowance for bad debt against our accounts receivable consistent with historical payment experience. Bad debt expense is included in general and administrative expense on our consolidated statements of operations. As of December 31, 2006, our allowance for bad debt was $510,000. No write-offs for bad debt were recorded against the allowance during the year ended December 31, 2006. Bad debt expense was $510,000 was for the year ended December 31, 2006. No bad debt expense was recorded for the years ended December 31, 2005 and 2004 because the vast majority revenue was recorded on a cash basis. Accounts receivable over 90 days will be written off 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.

Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recognized on a contract specific basis. Under certain contracts, our input, measured in terms of full-time equivalent level of effort or running a set of assays through our laboratory under a contractual protocol, triggers payment obligations and revenues are recognized as costs are incurred or assays are processed. Certain contracts have payment obligations that are triggered as milestones are complete, such as completion of a successful set of experiments. In these cases, revenues are recognized when the milestones are achieved.

Stock-based Compensation Expense

Through December 31, 2005, we accounted for stock-based payment transactions under Accounting Principles Board Opinion No. 25, or APB 25. On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R. *S*FAS 123R, which addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. SFAS 123R eliminates the ability to account for stock-based compensation transactions using the intrinsic value method under APB 25, and instead requires that such transactions be accounted for using a fair-value based method. SFAS 123R is a complex accounting standard, the application of which requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. We use the Black-Scholes valuation method, which requires the use of estimates such as stock price volatility and expected options lives, as well as expected option forfeiture rates, to value equity-based compensation. There is little historical evidence or guidance available with respect to developing these assumptions and models. Expected volatility is based on comparable peer data as well as historical volatility of our stock. The expected life of options granted is estimated based on historical option exercise and employee termination experience and peer group data.

We have elected the modified prospective transition method as permitted under SFAS 123R and, accordingly, prior periods have not been restated to reflect the impact of SFAS 123R. The modified prospective transition method requires that stock-based compensation expense be recorded for all new and unvested stock options that are ultimately expected to vest as the requisite service is rendered beginning on January 1, 2006. Stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted during the year ended December 31, 2006, as well as stock options granted prior to, but not yet vested as of January 1, 2006. As of December 31, 2006, total compensation expense related to non-vested stock options not yet recognized was $14.3 million, which is expected to be recognized over a period of 39 months.

Equity instruments granted to non-employees are valued using the Black-Scholes method and accounted for as prescribed by SFAS 123R and Emerging Issues Task Force, or EITF, Consensus No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or*

Services, and will be subject to periodic revaluation over their vesting terms.

Clinical Collaborator Costs

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.

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In addition to costs for research and development, under one of our collaboration agreements, we make annual payments resulting from the commercial launch of Onco*type* DX. These payments are recorded in cost of product revenues as a license payment. Expense is recorded ratably over the year before the relevant payment is made. However, either party may terminate the agreement upon 30 days prior written notice. If this collaborative agreement were not cancelable, a liability for the entire stream of remaining payments of $2.2 million would be recorded and expense would be recognized ratably through 2011.

Results of Operations

Years Ended December 31, 2006 and 2005

Revenues. Total revenues were $29.2 million for the year ended December 31, 2006 compared to $5.2 million for the year ended December 31, 2005. Product revenues from Onco*type* DX were $27.0 million for the year ended December 31, 2006 compared to $4.8 million for the comparable period in 2005. Approximately 40% of product revenue for the year ended December 31, 2006 was recorded on an accrual basis compared to 7% for the comparable period in 2005. The balance of product revenue was recognized upon cash collection. Product revenue from Medicare was $12.7 million, representing 47% of total product revenue for the year ended December 31, 2006; we had no product revenue from Medicare in 2005. This increase was a result of the February 27, 2006 effective coverage date for Medicare patients and the receipt of payments for tests provided to Medicare patients prior to the effective coverage date.

Contract revenues were $2.2 million for the year ended December 31, 2006 compared to $379,000 for the comparable period in 2005. 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 reflected the initiation of the collaboration with Aventis, Inc., and the Eastern Cooperative Oncology Group as well as ongoing work with Bristol-Myers Squibb and ImClone Systems.

Cost of Product Revenues. For the year ended December 31, 2006, cost of product revenues was $9.9 million for Onco*type* DX, consisting of tissue sample processing costs of $7.7 million and license fees of $2.2 million. For the year ended December 31, 2005, cost of product revenues was $6.2 million, consisting of tissue sample processing costs of $5.5 million and license fees of $786,000. Test volume for the year ended December 31, 2006 more than doubled over the prior year, resulting in a decrease in the cost per test delivered. During the years ended December 31, 2006 and 2005, we recorded tissue sample processing costs for Onco*type* DX that included direct material costs, direct labor costs, equipment costs, shipping costs and other infrastructure costs. All costs recorded for tissue sample processing in those periods represent the cost of all the tests processed regardless of whether revenue was recognized with respect to that test. License fees were recorded in cost of product revenues for contractual obligations and royalties due on product revenues.

Research and Development Expenses. Research and development expenses increased to $12.8 million for the year ended December 31, 2006 from $9.5 million for the comparable period in 2005. The increase in research and development expenses was primarily due to a $1.7 million increase in personnel and related costs, a $1.2 million increase in collaboration expense and a $595,000 increase in infrastructure-related expense. We expect that our research and development expenses will increase as our investment in developing tests for cancers, including cancers other than breast cancer, continues.

Selling and Marketing Expenses. Selling and marketing expenses increased to $24.6 million for the year ended December 31, 2006 from $15.3 million for the comparable period in 2005. The $9.3 million increase in selling and marketing expenses was primarily due a $4.9 million increase in personnel related costs, mostly to expand our

domestic field sales organization, a $2.7 million increase in promotional field and marketing expense, $900,000 in higher travel-related expenses associated with field personnel and a $698,000 increase in infrastructure-related expense. We expanded our domestic field sales force to support Onco*type* DX in the second half of 2006 and we expect that selling and marketing expenses will continue to increase in future periods as we continue to expand our sales force and conduct additional physician and patient education.

General and Administrative Expenses. General and administrative expenses increased to $12.8 million for the year ended December 31, 2006 from $6.5 million for the comparable period in 2005. The $6.3 million increase

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in general and administrative expenses included a $2.6 million increase in personnel costs, $1.2 million in higher billing and collection fees paid to third-party billing and collection vendors, an increase of $1.1 million in legal and accounting fees, an increase of $510,000 in expense to establish a bad debt reserve against accounts receivable, an increase of $335,000 in insurance related costs and an increase of $292,000 in costs for third-party service providers related to being a public company, including investor relations. We expect general and administrative expenses to continue to increase as we spend more on fees for billing and collections due to revenue growth and continue to incur costs associated with regulatory matters and other expenses associated with the growth of our business.

Interest Income. Interest income was $2.5 million for the year ended December 31, 2006 compared to $1.2 million for the comparable period in 2005, reflecting higher average cash balances and higher market yields.

Interest Expense. Interest expense was $446,000 for the year ended December 31, 2006 compared to $258,000 for the comparable period in 2005, reflecting interest expense incurred on our equipment financing line established at the end of March 2005 under which draws have been made and interest expense has been incurred.

Years Ended December 31, 2005 and 2004

Revenues. Product revenues were $5.2 million for the year ended December 31, 2005, as compared to $327,000 for the year ended December 31, 2004. Product revenues for the year ended December 31, 2005 were $4.8 million, as compared to $227,000 in the comparable period in 2004. Product revenues were primarily recognized upon cash receipt. A portion of product revenue was recorded on an accrual basis for the first time in the fourth quarter of 2005.

Contract revenues were $379,000 for the year ended December 31, 2005, up from $100,000 in the comparable period in 2004. Contract revenues were for studies assessing our gene expression technology and initial collaborative work in gene selection with our pharmaceutical partners.

Cost of Product Revenues. For the year ended December 31, 2005, cost of product revenues was $6.2 million for Onco*type* DX, consisting of tissue sample processing costs of $5.5 million and license fees of $786,000. For the year ended December 31, 2004, cost of product revenues was $1.8 million, consisting of tissue sample processing costs of $1.3 million and license fees of $477,000. During the years ended December 31, 2005 and 2004, we recorded costs for Onco*type* DX that included direct material costs, direct labor costs, equipment costs and other infrastructure costs. All costs recorded for tissue sample processing in those years represent the cost of all the tests processed regardless of whether revenue was recognized with respect to that test. License fees were recorded in cost of product revenues for contractual obligations and royalties due on product revenues.

Research and Development Expenses. Research and development expenses decreased to $9.5 million for the year ended December 31, 2005, from $10.0 million for the comparable period in 2004. The decrease in research and development expenses was primarily due to $1.5 million in decreased costs for clinical development programs studying distant survival and chemotherapy benefits in early stage breast cancer patients and decreased license fees of $645,000 partially offset by increased personnel costs of $1.4 million and an increase of $217,000 in facilities, depreciation and other general expenses.

Selling and Marketing Expenses. Selling and marketing expenses increased to $15.3 million for the year ended December 31, 2005, from $9.9 million for the comparable period in 2004. The $5.4 million increase primarily reflected an increase of $3.1 million in personnel related costs, mostly to establish a domestic field sales organization, and $985,000 in higher travel expenses associated with field sales personnel, an increase of $903,000 in field promotional and marketing expenses and an increase of $458,000 in facilities, depreciation and other general expenses.

General and Administrative Expenses. General and administrative expenses increased to $6.5 million for the year ended December 31, 2005 from $3.9 million for the comparable period in 2004. The increase in general and administrative expenses reflected an increase of $1.2 million in personnel costs, stock-based compensation and consulting costs, an increase of $626,000 in billing and collections fees paid to third-party billing and collection vendors and a $178,000 increase in insurance-related costs. These higher costs were offset in part by a $383,000 decrease in costs related to infrastructure support.

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Interest Income and Other Income/Expense. Interest income was $1.2 million for the year ended December 31, 2005, compared with $295,000 in the comparable period in 2004. This $946,000 increase was due to higher average cash balances from our December 2004 preferred stock financing, our September 2005 public offering and higher interest rates during the year ended December 31, 2005. Other expense was $1,000 for the year ended December 31, 2005, compared with $20,000 for the comparable period in 2004.

Interest Expense. Interest expense was comprised of the interest on deferral of contractual payments under a collaboration agreement and interest indebtedness. Interest expense increased to $258,000 for the year ended December 31, 2005, from $4,000 in the comparable period in 2004. The increase resulted from the initiation of an equipment financing line established in March 2005 under which draws have been made and interest expense has been incurred. No such arrangement existed in the prior year.

Liquidity and Capital Resources

Since our inception in August 2000, we have incurred significant losses and, as of December 31, 2006, we had an accumulated deficit of approximately $125.1 million. We have not yet achieved profitability and anticipate that we will continue to incur net losses for at least the next two years. We expect that our research and development, selling and marketing and general and administrative expenses will continue to grow and, as a result, we will need to generate significant product revenues to achieve profitability. We may never achieve profitability.

Sources of Liquidity

Since our inception through December 31, 2006, we have received net proceeds of $103.2 million from the sale of preferred stock and $575,000 from the issuance of common stock to employees, consultants and directors in connection with the exercise of stock options. In October 2005, we completed an initial public offering and a concurrent private placement of our common stock, resulting in net proceeds of $58.5 million. Purchases of equipment and leasehold improvements have been partially financed through loans. At December 31, 2006, we had cash, cash equivalents and short-term investments of $44.2 million and debt under our equipment loan of $7.3 million. At December 31, 2005, we had cash, cash equivalents and short-term investments of $69.5 million and debt under our equipment loan of $3.7 million.

Cash Flows

As of December 31, 2006, we had $44.2 million in cash, cash equivalents and short-term investments, compared to $69.5 million at December 31, 2005. This decrease of $25.3 million was due primarily to cash used in operating activities of $20.8 million and purchases of property, equipment and leasehold improvements of $8.4 million, partially offset by net proceeds from our equipment loans of $3.6 million.

Net cash used in operating activities was $20.8 million for the year ended December 31, 2006, compared to $27.6 million for the year ended December 31, 2005. The decrease in cash used in operating activities of $6.8 million was primarily due to a decrease in net loss, excluding non-cash adjustments, of $5.4 million, a decrease in prepaid expenses and other assets of $599,000 and an increase in accounts payable and accrued liabilities of $584,000. The decrease in net loss resulted from a $22.2 million increase in revenues for Onco*type* DX, a $1.8 million increase in revenue from pharmaceutical collaborators, and a $1.2 million increase in interest income, partially offset by a $22.6 million increase in operating expenses.

Net cash provided by investing activities was $13.1 million for the year ended December 31, 2006, compared to net cash used in investing activities of $54.2 million for the year ended December 31, 2005. This increase of $67.3 million

was due to a decrease of $72.1 million in short-term investments offset by a $5.4 million increase in cash used to acquire property, equipment and leasehold improvements.

Net cash provided by financing activities during the year ended December 31, 2006 was $3.8 million, compared to $62.4 million for the year ended December 31, 2005. Amounts for 2006 represented $3.6 million of net proceeds from our equipment loan and $179,000 of net proceeds from issuance of common stock related to stock option exercises. Amounts in the year ended December 31, 2005 included net proceeds from our initial public

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offering of $53.5 million, proceeds from our private placement with Incyte of $5.0 million and net proceeds from our equipment loan of $3.7 million.

Off-Balance Sheet Activities

As of December 31, 2006, we have not engaged in any off-balance sheet activities.

Contractual Obligations

As of December 31, 2006, we had the following contractual commitments:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
			(In thousands)		
Notes payable obligations	$ 8,468	$ 3,223	$ 5,007	$ 238	$
Operating lease obligations	4,026	730	1,531	1,626	139
Total	$ 12,494	$ 3,953	$ 6,538	$ 1,864	$ 139

In March 2005, we entered into an arrangement to finance the acquisition of laboratory equipment, computer hardware and software, leasehold improvements and office equipment. In connection with this arrangement, we granted the lender a security interest in the assets purchased with the borrowed amounts. We could not prepay any amounts owed until April 2006, at which point we could prepay all, but not part, of the amounts owing under the arrangement so long as we also pay a 6% premium on the remaining payments. This premium is reduced to 5% in 2007 and 4% in 2008. As of December 31, 2006, borrowings under this arrangement were $7.3 million at an annual interest rate of 10.23%, 10.30%, 10.49%, 10.56%, 10.65%, 11.01%, 11.18% or 11.30%, depending upon the applicable note.

As December 31, 2006, we leased approximately 48,000 square feet of laboratory and office space under a lease we entered into in September 2005. The lease has a term of six years. As of December 31, 2006, we are required to make aggregate rent payments of $730,000 in 2007, $753,000 in 2008, $778,000 in 2009, $799,000 in 2010 and $966,000 in 2011 and thereafter, all of which are included in the table above.

In January 2007, we executed an agreement to lease approximately 48,000 square feet of additional laboratory and office space near the location we currently occupy. The lease has a term of six years. Under the new lease, we are required to make aggregate rent payments of $375,000 in 2007, $595,000 in 2008, $741,000 in 2009, $835,000 in 2010 and $1.0 million in 2011 and thereafter, which are not included in the table above.

In addition to the above, we are required to make a series of annual payments under one of our collaboration agreements beginning on the date that we commercially launched Onco*type* DX. The initial payment of $150,000 was made in January 2004. For a period of seven years on each anniversary of this first payment, we are required to make additional payments in increasing amounts. Payments of $150,000 and $300,000 were made in January 2005 and January 2006, respectively. We are required to make additional payments of $300,000 in 2007 and $475,000 in each of 2008 through 2011. However, either party may terminate the agreement upon 30 days prior written notice.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future and to make capital expenditures to keep pace with the expansion of our research and development programs and to scale up our commercial operations. It may take several years to move any one of a number of product candidates in early development through the development phase and validation phase to commercialization. We expect that our cash and cash equivalents will be used to fund working capital and for capital expenditures and other general corporate purposes, such as licensing technology rights, partnering arrangements for our tests outside the United States or reduction of debt obligations. We have spent approximately $6.8 million through December 31, 2006 for facility expansion and improvements and are considering an additional approximately $1.0 million in further facility improvements.

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The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the progress of our product development, regulatory requirements, commercialization efforts, the amount of cash used by operations and progress in reimbursement. We expect that we will receive limited payments for Onco*type* DX billings in the foreseeable future. As reimbursement contracts with third-party payors are put into place, we expect an increase in the number and level of payments received for Onco*type* DX billings.

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

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

- the rate of progress in establishing reimbursement arrangements with third-party payors;
- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;
- the rate of progress and cost of research and development activities associated with expansion of Onco*type* DX for breast cancer;
- the rate of progress and cost of research and development activities associated with products in the research phase focused on cancers other than breast cancer;
- the cost of acquiring or achieving access to tissue samples and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products; and
- the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter.

We may also use cash to acquire or invest in complementary businesses, technologies, services or products. Until we can generate a sufficient amount of product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The issuance of equity securities may result in dilution to stockholders, and debt financing may involve restrictive covenants. We do not know whether additional funding will be available on acceptable terms, or 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 development programs or market development programs, which would lower the economic value of those programs to our company.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements,* or SFAS 157. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This Statement is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS 157 will have on our financial condition, results of operations and cash flows.

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In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS 109, *Accounting for Income Taxes.* FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We plan to adopt FIN 48 as of January 1, 2007 and are currently evaluating the effect that the adoption of FIN 48 will have on our financial condition, results of operations and cash flows.

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

We are exposed to interest rate risk primarily through our investment portfolio. Our marketable securities consist of high-quality debt securities with maturities beyond 90 days at the date of acquisition, which mature within one year or less. Our long-term investments consist of high-quality debt securities with maturities beyond one year. As of December 31, 2006, we had cash, cash equivalents and short-term investments totaling $44.2 million. Our investment policy calls for investments in short term, low risk, investment-grade instruments. Based on our portfolio content and our ability to hold investments to maturity, we believe that, if market interest rates were to increase immediately and uniformly by 10% from levels at December 31, 2006, the decline in fair value would not be material.

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

Genomic Health, Inc.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Genomic Health, Inc.

We have audited the accompanying consolidated balance sheets of Genomic Health, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations, convertible preferred stock and stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genomic Health, Inc. at December 31, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 9 to the consolidated financial statements, under the heading Stock-Based Compensation, the Company adopted Statement of Financial Accounting Standards No. 123(R), Share-Based Payment , effective January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Genomic Health, Inc. s internal control over financial reporting as of December 31, 2006, 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 14, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 14, 2007

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Genomic Health, Inc.

We have audited management s assessment, included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting, that Genomic Health, Inc. maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of Genomic Health Inc. 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, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management s assessment that Genomic Health, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Genomic Health, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006 and 2005, and the related consolidated statements of operations, convertible preferred stock and stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2006 and our report dated March 14, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 14, 2007

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GENOMIC HEALTH, INC.

Consolidated Balance Sheets

	December 31, 2006	2005
	(In thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,926	$ 18,839
Short-term investments	29,289	50,688
Accounts receivable (net of allowance for bad debt; 2006-$510, 2005-$0)	1,862	314
Prepaid expenses and other current assets	1,609	1,584
Employee note receivable		37
Total current assets	47,686	71,462
Property and equipment, net	9,421	3,597
Restricted cash	500	500
Other assets	417	240
Total assets	$ 58,024	$ 75,799
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,523	$ 1,393
Accrued compensation	1,868	955
Accrued expenses and other current liabilities	1,474	1,364
Accrued license fees	907	585
Notes payable current portion	2,547	1,052
Deferred revenues current portion	710	238
Lease incentive obligations current portion	122	74
Total current liabilities	10,151	5,661
Notes payable long-term portion	4,726	2,621
Deferred revenues long-term portion	137	
Lease incentive obligations long-term portion	761	
Other liabilities	420	
Stockholders equity:		
Preferred stock, $0.0001 par value, 5,000,000 and none authorized, no shares issued and outstanding at December 31, 2006 and 2005		
Common stock, $0.0001 par value; 100,000,000 shares authorized, 24,548,060 and 24,470,981 shares issued and outstanding at December 31, 2006 and 2005, respectively	2	2
Additional paid-in capital	166,922	167,053

Deferred stock-based compensation		(3,297)
Accumulated other comprehensive income (loss)	8	(58)
Accumulated deficit	(125,103)	(96,183)
Total stockholders equity	41,829	67,517
Total liabilities and stockholders equity	$ 58,024	$ 75,799

See accompanying notes.

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GENOMIC HEALTH, INC.

Consolidated Statements of Operations

	Year Ended December 31,		
	2006	2005	2004
	(In thousands, except share and per share amounts)		
Revenues:			
Product revenues	$ 27,006	$ 4,823	$ 227
Contract revenues	2,168	379	100
Total revenues	29,174	5,202	327
Operating expenses:			
Cost of product revenues	9,908	6,249	1,828
Research and development	12,841	9,465	10,040
Selling and marketing	24,625	15,348	9,856
General and administrative	12,765	6,485	3,869
Total operating expenses	60,139	37,547	25,593
Loss from operations	(30,965)	(32,345)	(25,266)
Interest income	2,480	1,241	295
Interest expense	(446)	(258)	(4)
Other income (expense), net	11	1	(20)
Net loss	$ (28,920)	$ (31,361)	$ (24,995)
Basic and diluted net loss per share	$ (1.18)	$ (4.15)	$ (13.82)
Shares used in computing basic and diluted net loss per share	24,508,845	7,557,106	1,808,022

See accompanying notes.

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GENOMIC HEALTH, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)

	Convertible Preferred Stock		Common Stock		Additional	Deferred	Accumulated Other		Total Stockhol
	Shares	Amount	Shares	Amount	Paid-In Capital	Stock-based Compensation	Comprehensive Income (Loss)	Accumulated Deficit	Equity (Defici
			(In thousands, except share and per share amounts)						
nce at ember 31, 2003	29,936,839	$ 51,064	1,741,684	$	$ 280	$	$	$ (39,827)	$ (39,5
ance of common k to employees n exercise of k options at $0.66 1.38 per share for			222,531		143				1
ance of common k to consultants n exercise of k options at $0.66 1.38 per share for			1,169		1				
urchase of mon stock issued ounders			(14,223)						
ance of Series E vertible preferred k at $2.82 per e for cash (net of ance costs of 6)	18,543,980	52,148							
erred stock pensation					3,647	(3,647)			
ortization of rred stock pensation						191			1
k-based pensation related onsultant options loss and prehensive loss					53			(24,995)	(24,9
nce at ember 31, 2004	48,480,819	103,212	1,951,161		4,124	(3,456)		(64,822)	(64,1

ance of common k to employees n exercise of k options at $0.58 2.88 per share for			266,916		245				2
ance of common k to consultants n exercise of k options at $0.66 2.88 per share for			5,197		7				
ance of common k at $12.00 per e, net of issuance s			5,016,722		53,458				53,4
ance of common k to Incyte at 00 per share			416,666		5,000				5,0
version of erred stock into mon stock	(48,480,819)	(103,212)	16,814,319	2	103,210				103,2
k-based pensation related onsultant options					92				
erred stock pensation					917	(917)			
ortization of rred stock pensation						1,076			1,0
prehensive loss: loss								(31,361)	(31,3
nge in unrealized on investments							(58)		(
prehensive loss									(31,4
nce at ember 31, 2005			24,470,981	2	167,053	$ (3,297)	(58)	(96,183)	67,5
erred pensation assified upon tion of S 123R on ary 1, 2006					(3,297)	3,297			
ance of common k to employees n exercise of k options at $0.63 9.39 per share for			74,826		173				1

ance of common								
k to consultants								
n exercise of								
k options at $2.88								
share for cash		2,253		6				
k-based								
pensation related								
mployee stock								
ons				2,904				2,9
k-based								
pensation related								
onsultant stock								
ons				83				
prehensive loss:								
loss							(28,920)	(28,9
nge in unrealized								
on investments						66		
prehensive loss								(28,8
nce at								
ember 31, 2006	$	24,548,060	$ 2	$ 166,922	$	$ 8	$ (125,103)	$ 41,8

See accompanying notes.

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GENOMIC HEALTH, INC.

Consolidated Statements of Cash Flows

	2006	December 31, 2005	2004
		(In thousands)	
Operating activities			
Net loss	$ (28,920)	$ (31,361)	$ (24,995)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,579	1,522	1,008
Employee stock-based compensation	2,904	1,076	191
Non-employee stock-based compensation	83	92	53
Gain or loss on disposal of property and equipment	3	(31)	20
Changes in assets and liabilities:			
Accounts receivable	(1,548)	(314)	
Employee note receivable	37	76	(113)
Prepaid expenses and other current assets	(25)	(683)	(338)
Other assets	216	(107)	
Accounts payable	1,130	292	274
Accrued expenses and other liabilities	432	1,247	527
Accrued compensation	913	352	261
Deferred revenues	609	238	
Lease incentive obligations	809		
Net cash used in operating activities	(20,778)	(27,601)	(23,112)
Investing activities			
Purchase of property and equipment	(8,379)	(2,972)	(1,856)
Purchase of short-term investments	(40,068)	(50,688)	
Maturities of short-term investments	61,467		
Unrealized gains (losses) on investment securities	66	(58)	
Restricted cash		(500)	50
Net cash provided by (used in) investing activities	13,086	(54,218)	(1,806)
Financing activities			
Proceeds from notes payable	4,912	4,090	
Principal payments of notes payable	(1,312)	(417)	
Net proceeds from issuance of common stock	179	58,710	144
Net proceeds from issuance of convertible preferred stock			52,148
Repayment of long-term debt due to related party			(161)
Net cash provided by financing activities	3,779	62,383	52,131
Net increase (decrease) in cash and cash equivalents	(3,913)	(19,436)	27,213
Cash and cash equivalents at the beginning of period	18,839	38,275	11,062

Cash and cash equivalents at the end of period	$ 14,926	$ 18,839	$ 38,275
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 446	$ 258	$ 4
Non-cash transactions:			
Preferred stock converted to common upon initial public offering		103,212	

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2006

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc., or the Company, was incorporated in Delaware in August 2000. The Company was organized to deliver individualized genomic information to patients and their physicians to improve the quality of treatment decisions for patients with cancer. The Company s first test, Onco*type* DX, was launched in 2004 and is used for early stage breast cancer patients to predict the likelihood of cancer recurrence, the likelihood of patient survival within 10 years of diagnosis and the likelihood of chemotherapy benefit. The Company has incurred significant losses and expects to incur additional losses for at least the next two years as commercial and development efforts continue.

Initial Public Offering

On October 4, 2005, the Company closed an initial public offering of 5,016,722 shares of its common stock at $12.00 per share. Net proceeds from the offering after deducting underwriting discounts, commissions and expenses were $53.5 million. On the closing of the Company s initial public offering, all of the convertible preferred stock outstanding automatically converted into 16,160,273 shares of common stock.

An additional $5.0 million was raised on October 4, 2005, through the private sale of 416,666 shares common stock to Incyte Corporation, a related party. As of December 31, 2006, to the Company s knowledge, Incyte Corporation had divested its holdings in the Company s common stock. See Note 10 to the Company s consolidated financial statements for further information on related parties.

Principles of Consolidation

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

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements as of December 31, 2006 and 2005 and for the years ended December 31, 2006, 2005 and 2004 have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make judgments, assumptions and estimates that affect the amounts reported in the Company s consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Cash Equivalents and Short-term Investments

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company invests in money market securities through a major U.S. bank and is exposed to credit risk in the event of default by the financial institution to the extent of amounts recorded on the balance sheets.

The Company invests in short-term and long-term marketable securities, primarily corporate notes, government agencies, asset-backed securities and municipal bonds. The Company considers all investments with a maturity date less than one year as of the balance sheet date to be short-term investments. These securities are carried at estimated fair value with unrealized gains and losses included in stockholders equity. Those investments with a maturity date greater than one year as of the balance sheet date are considered to be long-term investments. All investments are available for sale.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Restricted Cash

In September 2005, the Company entered into a non-cancelable facilities lease with the facility owner that has a term of six years. In connection with this lease, the Company was required to secure a letter of credit, which totaled $500,000 and is classified as restricted cash on the balance sheet.

Fair Value of Financial Instruments

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

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 term of the lease, whichever is shorter.

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 as deferred rent and are recognized as reductions to rental expense on a straight-line basis over the term of the lease.

Intangible assets

Intangible assets with definite useful lives are recorded at cost, less accumulated amortization. Amortization is recognized over their estimated useful lives.

Impairment of Long-lived Assets

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

Research and Development

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

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

contracts with biopharmaceutical and pharmaceutical companies. Research and development costs are expensed as incurred.

Concentration of Risk

Cash, cash equivalents, short-term investments and accounts receivable are financial instruments which potentially subject the Company to concentrations of credit risk. The Company invests in debt instruments and in money market funds, and by policy, limits the amount in any one type of investment, other than securities issued or guaranteed by the U.S. Government. Through December 31, 2006, no material losses had been incurred. One major customer accounted for approximately 47% of the Company s product revenue for the year ended December 31, 2006; no revenue from this customer was recorded in 2005. This customer represented 59% of the Company s net accounts receivable balance as of December 31, 2006. Another major customer accounted for approximately 4% and 11% of the Company s revenue in 2006 and 2005, respectively. This customer represented 17% and 70% of the Company s accounts receivable balance as of December 31, 2006 and 2005, respectively.

Comprehensive Loss

The Company displays comprehensive loss and its components as part of the statements of stockholders equity. Other comprehensive loss consists entirely of unrealized gains and losses on investments.

Internal Use Software

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

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, 2006 and 2005.

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.

Stock-based Compensation

Through December 31, 2005, the Company accounted for stock-based payment transactions under Accounting Principles Board Opinion No. 25, or APB 25. On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R. SFAS 123R, which addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. SFAS 123R eliminates the ability to account for stock-based compensation transactions using the intrinsic value method under APB 25, and instead requires that such transactions be

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

accounted for using a fair-value based method. SFAS 123R is a complex accounting standard, the application of which requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Company uses the Black-Scholes valuation method, which requires the use of estimates such as stock price volatility and expected options lives, as well as expected option forfeiture rates, to value equity-based compensation. There is little historical evidence or guidance available with respect to developing these assumptions and models. Expected volatility is based on comparable peer data as well as historical volatility of the Company s stock. The expected life of options granted is estimated based on historical option exercise and employee termination experience and peer group data.

The Company has elected the modified prospective transition method as permitted under SFAS 123R and, accordingly, prior periods have not been restated to reflect the impact of SFAS 123R. The modified prospective transition method requires that stock-based compensation expense be recorded for all new and unvested stock options that are ultimately expected to vest as the requisite service is rendered beginning on January 1, 2006. Stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted during the year ended December 31, 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of December 31, 2006, total compensation expense related to non-vested stock options not yet recognized was $14.3 million, which is expected to be recognized over a period of 39 months.

Equity instruments granted to non-employees are valued using the Black-Scholes method and accounted for as prescribed by SFAS 123R and Emerging Issues Task Force, or EITF, Consensus No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and will be subject to periodic revaluation over their vesting terms.

Revenue Recognition

The Company derives its revenues from product sales and contract research arrangements. The Company operates in one industry segment. Product revenues are derived solely from the sale of the Onco*type* DX test. Third-party payors are billed upon generation and delivery of a Recurrence Score report to the physician.

The Company s product revenues for tests performed are recognized when the following criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. Criterion (2) is satisfied when the Company performs the test and generates and delivers a report to the physician. Determination of criteria (3) and (4) is based on management s judgments regarding the nature of the fee charged for products or services delivered and the collectibility of those fees. Product revenues where all criteria set forth above are not met are recognized on a cash basis when cash is received.

The Company generally bills third-party payors for Onco*type* DX upon generation and delivery of a Recurrence Score report to the physician. As such, the Company takes assignment of benefits and the risk of collection with the third-party payor. The Company usually bills the patient directly for amounts owed after multiple requests for payment have been denied or only partially paid by the insurance carrier. As a relatively new test, Onco*type* DX may be considered investigational by payors and not covered under their reimbursement policies. Consequently, the Company pursues case-by-case reimbursement where policies are not in place or payment history has not been established. As a result, at the time of delivery of the Recurrence Score to the physician, and in the absence of a reimbursement contract or sufficient payment history, collectibility cannot reasonably be assured and revenues are

therefore only recognized at the time cash is collected.

In 2006 the Company began accruing an allowance for bad debt against its accounts receivable consistent with historical payment experience. Bad debt expense is included in general and administrative expense on the Company s consolidated statements of operations. As of December 31, 2006, the Company s allowance for bad debt was $510,000. No write-offs for bad debt were recorded against the allowance during the year ended December 31, 2006. Bad debt expense was $510,000 was for the year ended December 31, 2006. No bad debt

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

expense was recorded for the years ended December 31, 2005 and 2004 because the vast majority of revenues were recorded on a cash basis. Accounts receivable over 90 days will be written off 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.

Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recognized on a contract specific basis. Contract revenues are recorded on an accrual basis as the contractual obligations are completed. 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 laboratory under a contractual protocol, triggers payment obligations and revenues are recognized as costs are incurred or assays are processed. Certain contracts have payment obligations that are triggered as milestones are complete, such as completion of a successful set of experiments. In these cases, revenues are recognized when the milestones are achieved.

Recently Issued Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS 157. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This Statement is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its financial condition, results of operations and cash flows.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS 109, *Accounting for Income Taxes.* FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company will adopt FIN 48 as of January 1, 2007 and is currently evaluating the effect that the adoption of FIN 48 will have on its financial condition, results of operations and cash flows.

Note 2. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period without consideration for potential common shares. Diluted net loss per share is computed by dividing the loss by the weighted-average number of common shares outstanding for the period less the weighted-average unvested common shares subject to repurchase and dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock and options to purchase stock are considered to be potential common shares and are only included in the calculation of diluted loss per share when their effect is dilutive.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Year Ended December 31,		
	2006	2005	2004
	(In thousands, except share and per share data)		
Historical			
Numerator:			
Loss applicable to common stockholders	$ (28,920)	$ (31,361)	$ (24,995)
Denominator:			
Weighted-average common shares outstanding	24,508,845	7,557,106	1,808,022
Basic and diluted loss per share	$ (1.18)	$ (4.15)	$ (13.82)
Historical outstanding dilutive securities not included in diluted net loss per share calculation			
Preferred stock			16,160,273
Options to purchase common stock	2,940,803	2,021,276	1,423,508
	2,940,803	2,021,276	17,583,781

Note 3. Collaboration and Specimen Transfer Agreements

The Company has entered into a variety of specimen transfer and collaboration agreements relating to its development efforts. The Company recorded collaboration expenses of $1.5 million, $333,000 and $1.1 million for the years ended December 31, 2006, 2005 and 2004, respectively, relating to services provided in connection with these agreements. In addition to these expenses, certain agreements contain provisions for royalties from inventions resulting from these collaborations.

At December 31, 2006, future milestone payments, exclusive of royalty payments, relating to the launch and commercialization of Onco*type* DX total approximately $2.2 million and are payable as follows (in thousands):

	Milestone Payments
January 2007	$ 300
January 2008	475
January 2009	475
January 2010	475
January 2011	475
Total	$ 2,200

If at any time the Company discontinues the sale of commercial products or services resulting from the collaboration, no future milestone payments will be payable and the Company will have no further obligation under the agreement. If the Company s cash balance is less than $5.0 million on the due date of any the milestone payments, the Company may be able to defer any current milestone payment due for a period of up to 12 months.

In addition, the Company has secured certain options and rights relating to any joint inventions arising out of the collaborations.

Note 4. Commercial Technology Licensing Agreements

The Company is a party to various agreements under which it licenses technology on a nonexclusive basis in the field of human diagnostics. Access to these licenses enables the Company to process its laboratory tests for

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Onco*type* DX. Payments under these agreements for the years ended December 31, 2006, 2005 and 2004 were $2.2 million, $786,000 and $477,000, respectively, and were included in cost of product revenues.

Note 5. Short-term Investments

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

	December 31, 2006			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Debt securities of U.S. government agencies	$ 9,082	$ 3	$	$ 9,085
Corporate debt securities	20,199	5		20,204
Total	$ 29,281	$ 8	$	$ 29,289

	December 31, 2005			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Debt securities of U.S. government agencies	$ 14,625	$	$ (8)	$ 14,617
Corporate debt securities	31,326		(43)	31,283
Asset-backed securities	4,795		(7)	4,788
Total	$ 50,746	$	$ (58)	$ 50,688

The amortized cost and estimated fair value of available-for-sale securities by contractual maturity at December 31, 2006 was as follows:

	December 31, 2006	
	Cost	Market Value
	(In thousands)	
Due in one year or less	$ 29,281	$ 29,289

Note 6. Property and Equipment

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

	December 31,	
	2006	2005
	(In thousands)	
Computer equipment and software	$ 1,264	$ 1,137
Lab equipment	7,016	5,467
Furniture and fixtures	280	205
Leasehold improvements	7,296	343
Construction in progress	122	450
	15,978	7,602
Less accumulated depreciation and amortization	(6,557)	(4,005)
	$ 9,421	$ 3,597

For the years ended December 31, 2006, 2005 and 2004, the Company recorded depreciation and amortization expense of $2.6 million, $1.5 million and $1.0 million, respectively.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Commitments

Notes Payable

In March 2005, the Company entered into an arrangement to finance the acquisition of laboratory equipment, computer hardware and software, leasehold improvements and office equipment. In connection with this arrangement, the Company granted the lender a security interest in the assets purchased with the borrowed amounts. The Company could not prepay any amounts owed until April 2006, at which point the Company could prepay all, but not part, of the amounts owing under the arrangement so long as it also pay a 6% premium on the remaining payments. This premium is reduced to 5% in 2007 and 4% in 2008. As of December 31, 2006, borrowings under this arrangement were $7.3 million at an annual interest rate of 10.23%, 10.30%, 10.49%, 10.56%, 10.65%, 11.01%, 11.18% or 11.30%, depending on the applicable note. According to the terms of the arrangement the Company is required to notify the lender if there is a material adverse change. The Company complied with all the material covenants of the finance arrangement during the years ended December 31, 2006 and 2005.

As of December 31, 2006, the Company s aggregate commitments under its financing arrangement were as follows (in thousands):

	Annual Payment Amounts
Years Ending December 31,	
2007	$ 3,223
2008	3,073
2009	1,934
2010	238
Total minimum payments	8,468
Less: interest portion	(1,195)
Present value of net minimum payments	7,273
Less: current portion of obligations	(2,547)
Long-term obligations	$ 4,726

Leases

During 2003, the Company entered into an agreement to extend its then existing sublease through May 31, 2005, wherein monthly rent beginning October 1, 2003, was modified to be $75,000 per month. During 2005, the Company entered into an additional agreement to extend the original four-year term of the sublease agreement through

February 28, 2006, wherein monthly rent beginning June 1, 2005 was modified to $40,000 per month. As part of this 2005 agreement, the Company agreed to sublease additional adjacent premises effective February 8, 2005 through February 28, 2006 at a rate of $14,000 per month, with first and last monthly payments of $10,000 and $14,000, respectively. In September 2005, the Company entered into a non-cancelable lease directly with the facility owner for the entire 48,000 square feet of laboratory and office space that the Company currently occupies. The lease has a term of six years and included lease incentive obligations of $960,000, which are being amortized on a straight-line basis over the life of the lease.

Rent expense under all operating leases amounted to $810,000, $838,000 and $911,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Future non-cancelable commitments under operating leases at December 31, 2006, were as follows (in thousands):

	Annual Payment Amounts
Years Ending December 31,	
2007	$ 730
2008	753
2009	778
2010	799
2011	827
Thereafter	139
Total minimum payments	$ 4,026

Note 8. Convertible Preferred Stock and Stockholders Equity (Deficit)

Convertible Preferred Stock

In November 2000, January 2001, March 2001, March through November 2002, and February through December 2004 the Company completed private placements for the sale of 7,935,000, 15,675,674, 2,252,252, 4,073,913 and 18,543,980 shares of Series A, B, C, D and E convertible preferred stock, respectively, resulting in gross proceeds of $7.9 million, $29.0 million, $5.0 million, $9.4 million and $52.3 million, respectively.

On October 4, 2005, the Company completed its initial public offering of 5,016,722 shares of common stock at a price to the public of $12.00 per share. Upon consummation of the offering, all 48,480,819 outstanding shares of preferred stock converted into 16,160,273 of shares of common stock and a dividend of 654,046 common shares was distributed to the stockholders on conversion.

Note 9. Common Stock and Equity Plans

Common Stock

As of December 31, 2006, the Company had 24,548,060 shares of common stock outstanding. Common stock reserved for issuance as of December 31, 2006 is as follows:

Options outstanding	2,940,803
Future option grants	3,258,436

Dividend

On September 8, 2005, the board of directors of the Company declared a conditional dividend of 791,210 shares of common stock, which was allocated upon the closing of the Company s initial public offering on a pro rata basis to all of the Company s stockholders and option holders of record as of September 28, 2005. The Company issued 740,030 shares to its stockholders pursuant to this dividend at the closing of the initial public offering on October 4, 2005, less an aggregate of 86 shares for which cash was paid in lieu of fractional interests, and the number of shares underlying outstanding stock options were increased by approximately 51,080 shares, less any fractional shares resulting from such adjustment. The dividend has been given retroactive effect in the accompanying consolidated financial statements.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Reverse Stock Split

On September 23, 2005, the Company effected a 1-for-3 reverse stock split of its common stock. All share and per share amounts have been retroactively restated in the accompanying consolidated financial statements and notes for all periods presented.

2005 Stock Incentive Plan

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

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

Under the 2005 Plan, each outside director who joins the board after the effective date of the 2005 Plan will receive an automatic nonstatutory stock option grant that vests at a rate of 25% at the end of the first year, with the remaining balance vesting monthly over the next three years. On the first business day following the annual meeting of the Company s stockholders, each outside director who is continuing board service and who was not initially elected to the board at the annual meeting will receive an additional nonstatutory stock option grant, which will vest in full 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 appreciation rights, and stock units granted under the 2005 Plan are governed by restricted stock agreements, SAR agreements, and stock unit agreements between the Company and recipients of the awards. Terms of the agreements are determined by the Compensation Committee.

2001 Stock Incentive Plan

The Company s 2001 Stock Incentive Plan, or 2001 Plan, was terminated upon completion of the Company s initial public offering in October 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.

Adoption of SFAS 123R

Until December 31, 2005, the Company followed APB 25 to account for employee stock options using the intrinsic value method. Under APB 25, no compensation expense is recognized when the exercise price of the

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company s employee stock options equals the market price of the underlying stock on the date of grant. On January 1, 2006, the Company adopted SFAS 123R, which addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. SFAS 123R eliminates the ability to account for stock-based compensation transactions using the intrinsic value method under APB 25, and instead requires that such transactions be accounted for using a fair-value based method. The Company uses the Black-Scholes option valuation model to value stock options under SFAS 123R.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards.* The Company has elected to adopt the alternative transition method provided in the FASB Staff Position for calculating the tax effects (if any) of stock-based compensation expense pursuant to SFAS 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool, or APIC pool, related to the tax effects of employee stock-based compensation, and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects (if any) of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123R.

Employee stock-based compensation expense recognized for the year ended December 31, 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company recorded employee stock-based compensation expense of $2.9 million for the year ended December 31, 2006 as a result of the adoption of SFAS 123R. The following table presents the impact of the adoption of SFAS 123R on selected statements of operations line items for the year ended December 31, 2006:

	For the Year Ended December 31, 2006 (In thousands)
Cost of product revenues	$ 167
Research and development	821
Selling and marketing	779
General and administrative	1,137
Total	$ 2,904

As a result of adopting SFAS 123R on January 1, 2006, the Company s net loss for year ended December 31, 2006 was $1.8 million higher than if it had continued to account for stock-based compensation under APB 25. Basic and diluted net loss per share for the year ended December 31, 2006 was $0.07 higher than if the Company had continued to account for stock-based compensation under APB 25.

Stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted during the year ended December 31, 2006, as well as stock options granted prior to, but not yet vested

as of, January 1, 2006. As of December 31, 2006, total compensation expense related to non-vested stock options not yet recognized was $14.3 million, which is expected to be allocated to expenses over a remaining vesting period of 39 months.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Pro Forma Information for Period Prior to Adoption of SFAS 123R

The following pro forma net loss and loss per share were determined as if the Company had accounted for employee stock-based compensation for its employee stock option plans under the fair value method prescribed by SFAS 123:

	Year Ended December 31,	
	2005	2004
	(In thousands, except per share amounts)	
Net loss as reported	$ (31,361)	$ (24,995)
Add: Total stock-based employee compensation expense included in net loss	1,076	191
Deduct: Total stock-based employee compensation expense determined under the fair-value based method for all awards	(1,482)	(320)
Net loss, pro forma	$ (31,767)	$ (25,124)
Net loss per share:		
Basic and diluted, pro forma	$ (4.20)	$ (13.90)

Valuation Assumptions

The employee stock-based compensation expense recognized under SFAS 123R and presented in the pro forma disclosure required under SFAS 123 was determined using the Black-Scholes option valuation model. Option valuation models require the input of highly subjective assumptions and these assumptions can vary over time. Expected volatility is based on comparable peer data as well as the historical volatility of the Company s stock. The expected life of options granted is estimated based on historical option exercise and employee termination experience and comparable peer data. The risk-free interest rate is estimated using rates available on U.S. Treasury securities with a remaining term approximating the expected life of the options. 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 the assumptions used in calculating such values during each fiscal period are as follows:

	Year Ended December 31,		
	2006	2005	2004
Volatility factor	68%	77%	80%
Risk-free interest rate	4.76%	4.00%	2.80%
Dividend yield	0%	0%	0%

Expected life of options	5.5 years	4.8 years	4.0 years
Weighted-average fair value	$ 10.27	$ 6.39	4.98

Stock Options Granted to Non-employees

The Company grants options to consultants from time to time in exchange for services performed for the Company. During the years ended December 31, 2006, 2005 and 2004, the Company granted options to purchase

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2,850, 10,172 and 8,333 shares, respectively, of common stock to consultants. The fair value of these option grants was determined using the Black-Scholes option pricing model using the following assumptions:

	Year Ended December 31,		
	2006	**2005**	**2004**
Volatility factor	70%	75%	80%
Risk-free interest rate	4.80%	4.00%	2.40%
Dividend yield	0%	0%	0%
Expected life of options	10 years	10 years	10 years

In general, the options vest over the contractual period of the consulting arrangement and, therefore, the Company will revalue the options periodically and record additional compensation expense related to these options over the remaining vesting period. During the years ended December 31, 2006, 2005 and 2004, compensation expense related to these options was $83,000, $92,000 and $53,000, respectively.

Stock Option Activity

The following is a summary of option activity for the years ended December 31 2006, 2005 and 2004:

		Outstanding Options	
	Shares Available for Grant	**Number of Shares**	**Weighted-Average Exercise Price**
Balance at December 31, 2003	1,541,248	710,470	$ 0.74
Options granted	(942,453)	942,453	$ 2.18
Options exercised		(223,700)	$ 0.64
Options cancelled	5,715	(5,715)	$ 0.96
Balance at December 31, 2004	604,510	1,423,508	$ 1.71
Options authorized	5,000,000		
Options granted	(877,606)	877,606	$ 8.48
Options exercised		(272,113)	$ 0.93
2001 Plan shares expired	(443,998)		
Options cancelled	7,725	(7,725)	$ 1.92
Balance at December 31, 2005	4,290,631	2,021,276	$ 4.75
Options granted	(1,068,105)	1,068,105	$ 16.59
Options exercised		(77,079)	$ 2.36
2001 Plan shares expired	(35,589)		
Options cancelled	71,499	(71,499)	$ 5.94

Balance at December 31, 2006	3,258,436	2,940,803	$ 9.10

The intrinsic value of stock options exercised during 2006, 2005 and 2004 was $948,000 $942,000 and $160,000 respectively. The estimated fair value of options vesting in 2006, 2005 and 2004 was $2.7 million, $1.6 million and $436,000, respectively.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes information concerning outstanding and exercisable options under the 2001 and 2005 Plans as of December 31, 2006:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Number Outstanding	Weighted-Average Years Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$0.58 - $1.33	582,609	6.61	$ 1.10	403,319	$ 1.01
$2.88 - $2.88	516,773	8.02	$ 2.88	239,007	$ 2.88
$3.17 - $3.17	69,348	2.92	$ 3.17	34,674	$ 3.17
$9.39 - $9.39	610,209	8.92	$ 9.39	148,059	$ 9.39
$9.55 - $17.24	487,409	8.85	$ 12.14	35,429	$ 10.51
$18.89 - $22.45	674,455	9.92	$ 18.93		$
	2,940,803			860,488	

At December 31, 2006, the aggregate intrinsic value of the outstanding options was $28.2 million and the aggregate intrinsic value of the exercisable options was $13.1 million. The weighted-average remaining contractual life for exercisable options was 7.11 years.

Deferred Stock-based Compensation

During 2004, stock options were granted with exercise prices that were equal to the estimated fair value of the common stock on the date of grant as determined by the Board of Directors. Subsequent to the commencement of the initial public offering process, the Company reassessed the fair value of its common stock and determined that options granted from January 2004 through September 2005 were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. Accordingly, deferred stock-based compensation of $3.6 million was recorded during 2004 in accordance with APB 25 and presented as a separate component of stockholder s equity. In the year ended December 31, 2005, an additional $917,000 of deferred stock-based compensation was recorded. The Company recorded stock-based compensation expense of $1.1 million and $191,000, for the years ended December 31, 2005 and 2004, respectively.

In accordance with the provisions of SFAS 123R, on January 1, 2006 the Company reversed the balance in deferred compensation to additional paid-in capital on its balance sheet.

Note 10. Related Party Transactions

During 2000 and 2001 Incyte Corporation purchased shares of the Company s Series A Preferred Stock and Series C Preferred Stock for an aggregate purchase price of $6.0 million. The Company has two active agreements with Incyte that were entered into in March 2001 in connection with the sale of convertible preferred stock to Incyte; a LifeSeq collaborative agreement and a patent license agreement. The Company also entered into a collaboration and technology transfer agreement with Incyte and a Proteome BioKnowledge Library license agreement with Proteome, Inc., a then wholly owned subsidiary of Incyte, both of which have been terminated. Under these agreements, the Company paid Incyte database access fees of $1.0 million in 2004 and incurred royalties expense of $2,000, $48,000 and $270,000 in 2004, 2005 and 2006, respectively.

In connection with the completion of the Company s initial public offering on October 4, 2005, Incyte s shares of the Company s preferred stock were converted into common stock. Additionally, in connection with its initial public offering, the Company exercised an election under which Incyte was required to acquire an additional $5.0 million of the Company s common stock. One of the Company s directors is also director of Incyte and holds shares, directly or beneficially, of both companies. As of December 31, 2006, Incyte had completely divested its holdings in the Company s common stock.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 11. Income Taxes

The Company has not recognized a provision for income taxes for any of the periods presented because the Company has incurred operating losses to date.

As of December 31, 2006 and 2005, the Company had deferred tax assets of approximately $50.7 million and $39.4 million, respectively. Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately $11.3 million, $12.3 million and $10.1 million during the years ended December 31, 2006, 2005 and 2004, respectively. Deferred tax assets primarily relate to net operating loss and tax credit carryforwards.

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

	December 31,	
	2006	2005
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 45,503	$ 36,157
Capitalized costs	1,310	1,428
Research tax credits	2,684	1,871
Other	1,170	(96)
Total deferred tax assets	50,667	39,360
Valuation allowance	(50,667)	(39,360)
Net deferred tax assets	$	$

As of December 31, 2006, the Company had federal and state net operating loss carryforwards of approximately $114.2 million and $111.1 million, respectively, and federal and state research and development tax credit carryforwards of approximately $1.6 million and $1.6 million, respectively. The net operating loss and tax credit carryforwards will expire at various dates beginning in 2013 if not utilized.

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

Note 12. Subsequent Events

In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space near the location the Company currently occupies. The lease has a term of six years and includes lease incentive obligations of $420,000, which are being amortized on a straight-line basis over the life of the lease. Under the new lease, the Company is required to make aggregate rent payments of $375,000 in 2007, $595,000 in 2008, $741,000 in 2009, $835,000 in 2010 and $1.0 million in 2011 and thereafter. In connection with this lease, the Company paid a cash security deposit of $151,000.

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GENOMIC HEALTH, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13. Selected Quarterly Financial Data (Unaudited)

The following table contains selected unaudited statement of operations information for each of the quarters in 2006 and 2005. 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)			
2006				
Revenue(1)	$ 5,060	$ 8,379	$ 7,119	$ 8,616
Net loss	(6,830)	(4,915)	(8,180)	(8,995)
Basic and diluted net loss per common share	$ (0.28)	$ (0.20)	$ (0.33)	$ (0.37)
2005				
Revenue	$ 442	$ 1,243	$ 1,592	$ 1,925
Net loss	(7,586)	(8,113)	(7,445)	(8,217)
Basic and diluted net loss per common share	$ (3.85)	$ (4.07)	$ (3.42)	$ (0.34)

The increases in revenue in first and second quarters of 2006 were attributable to increased demand for Onco*type* DX following clinical presentations at major symposia in December 2005 and February 2006, as well as the May 2006 publication of two peer-reviewed articles supporting the use and reimbursement of Onco*type* DX. In addition, several third-party payors, including National Heritage Insurance Company (NHIC), the local Medicare carrier for California with jurisdiction for claims submitted by the Company for Medicare patients, issued positive coverage determinations for the test.

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 principally due to the effect of the Company s issuing shares of its common stock during the year. Basic and diluted net loss per share decreased significantly from the third quarter of 2005 to the fourth quarter of 2005 due to the increase in outstanding common stock resulting from the Company s initial public offering on September 28, 2005.

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

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

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, 2006. In making this assessment, 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, management concluded that, as of December 31, 2006, our internal control over financial reporting was effective. Our independent registered public accounting firm, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an audit report on management s assessment of our internal control over financial reporting as well as on the effectiveness our internal control over financial reporting. The report on the audit of internal control over financial reporting appears on page 59.

(b) *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

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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 2007 Annual Meeting of Stockholders to be held on June 12, 2007, or Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption Executive Officers of the Registrant and is incorporated herein by reference.

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

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

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

Our Board of Directors has appointed an Audit Committee, comprised of Mr. Randall S. Livingston, as Chairman, Mr. Samuel D. Colella and Mr. Michael D. Goldberg. 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 Global Market and Securities and Exchange Commission rules and regulations.

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

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

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 caption Security Ownership of Certain Beneficial Owners and Management contained in the Proxy Statement.

Information about securities authorized for issuance under our equity compensation plans appears under the caption Equity Compensation Plan Information in the Proxy Statement. That portion of the Proxy Statement is incorporated by

reference into this report.

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

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

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

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

PART IV

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

(a) Documents filed as part of this report:

(1) Financial Statements

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

(2) Financial Statement Schedules

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

(3) Exhibits

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

(b) Exhibits

Exhibit No.	Description of Document
3(i)	Restated Certificate of Incorporation of the Company (incorporated by reference to exhibit 3.3 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
3(ii)	Amended and Restated Bylaws of the Company, as amended April 27, 2006 (incorporated by reference to exhibit 3(ii) to the Company s Current Report on Form 8-K filed on May 2, 2006.
4.1	Specimen Common Stock Certificate (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
4.2	Amended and Restated Investors Rights Agreement, dated February 9, 2004 between the Company and certain of its stockholders (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.1#	Form of Indemnification Agreement between the Company and its officers and directors (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.2#	

	2001 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.3#	2005 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File 333-126626), as amended, declared effective on September 28, 2005).
10.4.1	Sublease Agreement dated June 1, 2001 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.2	First Amendment to Sublease Agreement dated October 29, 2003 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).

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Exhibit No.	Description of Document
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.
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.
21.1	List of Subsidiaries (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1*	Power of Attorney (see page 84 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 Nos. 33-8238 and 34-47986, Final Rule: Management s Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed filed for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

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

# Indicates management contract or compensatory plan or arrangement.

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

(c) Financial Statements and Schedules

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

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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/ Randal W. Scott
Randal W. Scott, Ph.D.
Chief Executive Officer and
Chairman of the Board
(Principal Executive Officer)

Date: March 16, 2007

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/ Randal W. Scott Randal W. Scott, Ph.D.	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 16, 2007
/s/ G. Bradley Cole G. Bradley Cole	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2007
/s/ Kimberly J. Popovits Kimberly J. Popovits	President, Chief Operating Officer and Director	March 15, 2007
/s/ Julian C. Baker Julian C. Baker	Director	March 15, 2007
/s/ Brook H. Byers	Director	March 15, 2007

Brook H. Byers		
/s/ Fred E. Cohen	Director	March 15, 2007
Fred E. Cohen, MD., Ph.D.		

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Signature	Title	Date
/s/ Samuel D. Colella	Director	March 15, 2007
Samuel D. Colella		
/s/ Michael D. Goldberg	Director	March 15, 2007
Michael D. Goldberg		
/s/ Randall S. Livingston	Director	March 15, 2007
Randall S. Livingston		
/s/ Woodrow A. Myers	Director	March 15, 2007
Woodrow A. Myers Jr., MD		

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EXHIBIT INDEX

Exhibit No.	Description of Document
3(i)	Restated Certificate of Incorporation of the Company (incorporated by reference to exhibit 3.3 filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
3(ii)	Amended and Restated Bylaws of the Company, as amended April 27, 2006 (incorporated by reference to exhibit 3(ii) to the Company s Current Report on Form 8-K filed on May 2, 2006).
4.1	Specimen Common Stock Certificate (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
4.2	Amended and Restated Investors Rights Agreement, dated February 9, 2004 between the Company and certain of its stockholders (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.1#	Form of Indemnification Agreement between the Company and its officers and directors (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.2#	2001 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.3#	2005 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.1	Sublease Agreement dated June 1, 2001 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
10.4.2	First Amendment to Sublease Agreement dated October 29, 2003 between the Company and Corixa Corporation (incorporated by reference to the exhibit of the same number filed with Registration Statement on Form S-1 (File No. 333-126626), as amended, declared effective on September 28, 2005).
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.
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