GENOMIC HEALTH INC
Form 424B4
September 29, 2005

Table of Contents

PROSPECTUS

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-126626

5,016,722 Shares
Common Stock

This is an initial public offering of shares of common stock by Genomic Health, Inc. We are offering 5,016,722 shares of our common stock. No public market currently exists for our common stock.

Our common stock has been approved for quotation on the Nasdaq National Market under the symbol GHDX.

This investment involves risk. See Risk Factors beginning on page 7.

	Per Share	Total
Initial Public Offering Price	$ 12.00	$ 60,200,664
Underwriting Discount	$ 0.882	$ 4,424,749
Proceeds to Genomic Health, Inc. (before expenses)	$ 11.118	$ 55,775,915

We have granted the underwriters a 30-day option to purchase up to an additional 752,508 shares from us on the same terms and conditions as set forth above if the underwriters sell more than 5,016,722 shares of common stock in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about October 4, 2005.

Joint Book-Running Managers

JPMorgan **Lehman Brothers**

Piper Jaffray **Thomas Weisel Partners LLC**

JMP Securities

September 28, 2005

Table of Contents

individualized treatment decision physician orders test sample tracking pathology review RNA processing automated multi-gene analysis quantitative readout patient report reimbursement support

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TABLE OF CONTENTS

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any person to provide you with different information. This prospectus is not an offer to sell, nor is it an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date. Without limitation to the other restrictions referred to herein, this communication is directed only at (i) persons outside the United Kingdom; (ii) persons having professional experience in matters relating to investments who fall within the definition of investment professionals in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005; or (iii) high net worth bodies corporate, unincorporated associations and partnerships and trustees of high value trusts as described in Article 49(2) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. Without limitation to the other restrictions referred to herein, any investment or investment activity to which this communication relates is available only to, and will be engaged in only with, the persons referred to in (i)-(iii) above, and persons within the United Kingdom who receive this communication (other than persons who fall within (ii) or (iii) above) should not rely or act upon this communication.

Until October 23, 2005 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Table of Contents

PROSPECTUS SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider. Therefore, you should also read the more detailed information set out in this prospectus, including the consolidated financial statements and related notes appearing elsewhere in this prospectus, before investing in our common stock. References in this prospectus to we, us and our refer to Genomic Health, Inc. unless the context requires otherwise.

GENOMIC HEALTH, INC.

Our Business

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 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. Our first commercial test is focused on patients with early stage, node negative, or N-, estrogen receptor positive, or ER+, breast cancer who will be treated with hormonal therapy. Approximately half of the 230,000 patients expected to be diagnosed with breast cancer in the United States in 2005 are predicted to be early stage cancer patients that are N-, ER+, and it is customarily recommended that those patients be treated with hormonal therapy.

Many of the diagnostic factors currently used in connection with early stage breast cancer are subjective. We believe these factors have limited capability to predict future cancer recurrence. Under current treatment regimens, a large percentage of early stage breast cancer patients receive chemotherapy. According to a National Surgical Adjuvant Breast and Bowel Project, or NSABP, study published in 2004, the overall survival at 12 years in early stage breast cancer patients using only the hormonal therapy tamoxifen 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%. 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. 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 and by the College of American Pathologists. In 2004, over 500 tests were ordered by treating physicians. In December 2004, our validation study was published in *The New England Journal of Medicine* and the results of additional clinical trials were presented at the San Antonio Breast Cancer Conference. In the six months ended June 30, 2005, over 3,000 tests were ordered by treating physicians. As of June 30, 2005, Onco*type* DX has been ordered by over 1,400 physicians throughout the United States.

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. 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 chemotherapy benefit, and we are undertaking further studies to support this finding.

Table of Contents

Onco*type* DX has been clinically validated for N-, ER+, tamoxifen-treated breast cancer patients by two large independent studies. The first study, conducted with the NSABP and published in *The New England Journal of Medicine* in December 2004, demonstrated that the Recurrence Score quantifies the likelihood of cancer recurrence in early stage breast cancer patients receiving tamoxifen therapy. Patients in a pre-defined low Recurrence Score group were more than four times less likely to have a recurrence of breast cancer than patients in a pre-defined high Recurrence Score group (p-value<0.001, or 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. The second study, conducted with Northern California Kaiser Permanente in a community hospital setting and reported at the San Antonio Breast Cancer Conference in December 2004, demonstrated that the Recurrence Score correlates with breast cancer survival at 10 years. 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). An additional study, which was conducted with the NSABP, demonstrated that the Recurrence Score predicts the likelihood of chemotherapy benefit. This study was 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 in May 2005.

We are using the clinical development platform that we created in connection with Onco*type* DX to build a product pipeline. Our products under research and development include a second generation product in N-, ER+ breast cancer, as well as tests that can be utilized in N+ breast cancer patients and tests that can be used to predict responsiveness to other current treatments such as specific types of chemotherapies. We are also conducting research on colon, prostate, renal cell and lung cancers and melanoma. Over 550,000 treatment decisions are expected to be made in the United States in 2005 for patients diagnosed with early stages of breast cancer and these cancers. In addition, we plan to develop additional tests in collaboration with pharmaceutical partners for targeted therapies. For example, 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.

Revenues for clinical laboratory testing services 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, and patients. As a relatively new test, Onco*type* DX may be considered investigational by payors and not covered under their reimbursement policies. Upon commercialization of Onco*type* DX, we began working with third-party payors to establish reimbursement coverage policies. Currently, several regional payors, including Harvard Pilgrim Health Care, Inc. and Highmark Blue Cross Blue Shield, have issued policies supporting reimbursement for our test. In addition, Kaiser Foundation Health Plan, Inc. has entered into a national clinical laboratory services agreement to reimburse us for Onco*type* DX tests performed for their patients. Where policies are not in place, we pursue case-by-case reimbursement. Through this process, as of June 30, 2005, over 180 payors had reimbursed one or more Onco*type* DX tests.

Our selling and marketing strategy targets the oncology community, primarily medical and surgical oncologists. Our direct sales approach focuses on the clinical and economic benefits of Onco*type* DX and the scientific validation supporting our product. Our field staff has significant clinical oncology selling and marketing experience from leading biopharmaceutical, pharmaceutical and specialty reference laboratory companies, and we promote our product through marketing channels commonly used by the biopharmaceutical and pharmaceutical industries, such as sponsored continuing medical education, medical meeting participation and broad-based publication of our scientific and economic data.

Our Solution

We believe that physicians and patients are currently making crucial and expensive treatment decisions based on inadequate and often subjective information with limited understanding of the molecular profile of a

Table of Contents

patient s tumor. Our strategy is to identify treatment decisions that can benefit from, and be guided by, each patient s individual genomic information.

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 methods and processes for screening hundreds of genes at a time using minimal amounts of chemically preserved tissue embedded in blocks of paraffin wax. 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 tumor recurrence or progression. 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 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 and, consequently, design an individualized treatment plan.

Improved Economics of Cancer Care. We believe that improving the quality of treatment decisions can result in significant economic benefits. In early stage breast cancer, our data shows that many patients are misclassified as high or low risk under existing treatment guidelines. Many low risk patients misclassified as high risk receive toxic and expensive chemotherapy treatment regimens. Chemotherapy may cost in excess of $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.

Risks Associated With Our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. Those reasons could include failure to obtain reimbursement for Onco*type* DX from a sufficient number of third-party payors, regulation of our test by the U.S. Food and Drug Administration, failure to maintain and to protect our intellectual property assets, and inability to maintain current collaborations or enter into new collaborations with organizations in the cancer field.

We currently have only one product, which was first commercialized in January 2004. We have incurred $80.5 million in cumulative net losses from our inception in 2000, and we expect losses to continue for the foreseeable future. Our net loss for the six months ended June 30, 2005 was $15.7 million, and for the year ended December 31, 2004, was $25.0 million.

Table of Contents

We do not anticipate commercializing another product for at least several years, if at all. All of our product candidates other than those for breast cancer are in the clinical research phase. We are unable to predict the extent of future losses or when we will become profitable, if at all. Even if we succeed in developing and commercializing another product, we may never generate sufficient product revenues to achieve and then sustain profitability.

Private Share Sale to Incyte Corporation

Concurrent with the closing of this offering, we will exercise a put right and cause Incyte Corporation to purchase from us in a private sale $5.0 million of our common stock at a price per share equal to the initial public offering price. At the initial public offering price of $12.00 per share, Incyte will purchase from us 416,666 shares of our common stock.

CORPORATE INFORMATION

We were incorporated in Delaware in August 2000. Our principal executive offices are located at 301 Penobscot Drive, Redwood City, California 94063, and our telephone number is (650) 556-9300. Our website is *www.genomichealth.com*. Information on our website is not a part of this prospectus.

The Genomic Health logo and Onco*type* are our registered trademarks. We have applied to register our trademarks, Onco*type* DX and Recurrence Score, with the U.S. Patent and Trademark Office. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective holders.

Table of Contents

The Offering

Common stock offered by us	5,016,722 shares
Common stock to be outstanding after this offering	24,367,432 shares
Initial public offering price per share	$12.00
Use of proceeds	We intend to use the net proceeds for general corporate purposes, including working capital and capital expenditures. See Use of Proceeds.
Proposed Nasdaq symbol	GHDX

Unless otherwise stated, all information in this prospectus assumes:

a 1-for-3 reverse split of our common stock;

the automatic conversion of every three shares of our convertible preferred stock into one share of common stock upon the closing of this offering;

our distribution of 736,142 shares of our common stock (based on shares outstanding as of August 31, 2005) as a dividend to our stockholders prior to the date of this offering and a proportional adjustment to options outstanding as of the dividend distribution date to increase the aggregate number of shares subject to exercise thereunder by 55,068 shares; and

no exercise of the over-allotment option granted to the underwriters.

The number of shares of common stock to be outstanding immediately after this offering:

includes 18,197,987 shares of common stock outstanding as of August 31, 2005;

includes 736,142 shares of common stock issuable to our stockholders of record prior to the date of this offering (based on shares outstanding as of August 31, 2005), less an aggregate of 85 shares for which cash will be paid in lieu of fractional interests, in connection with the stock dividend described above that we expect to make upon the closing of this offering;

includes 416,666 shares that we will issue in a private sale to Incyte Corporation concurrent with the closing of this offering in connection with our exercise of a put right described elsewhere in this prospectus;

excludes 1,416,206 shares of common stock issuable upon the exercise of stock options outstanding as of August 31, 2005, at a weighted average exercise price of $1.91 per share; and

excludes 5,000,000 shares of common stock available for future issuance under our stock option plans following the date of this offering.

Several of our significant existing stockholders, including funds affiliated with Julian C. Baker, Felix J. Baker and Integral Capital Partners VI, L.P. or their affiliates, have indicated an interest in purchasing up to an aggregate of 500,000 shares of our common stock in this offering, less any shares sold to our employees pursuant to our directed share program. However, because indications of interest are not binding upon us or the prospective purchasers, these stockholders may not acquire any shares in this offering.

Table of Contents

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table presents our summary consolidated historical financial information. You should read this information together with the consolidated financial statements and related notes and the information under Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

	Period from August 22, 2000 (inception) to Dec. 31, 2000	Year Ended December 31,				Six Months Ended June 30,	
		2001	2002	2003	2004	2004	2005
	(In thousands, except share and per share data)					(Unaudited)	
Consolidated Statements of Operations Data:							
Revenues:							
Product revenues	$	$	$	$	$ 227	$ 33	$ 1,585
Contract revenues				125	100		100
Total revenues				125	327	33	1,685
Operating expenses(1):							
Cost of product revenues					1,828	931	2,874
Research and development	169	11,080	7,053	9,069	10,040	5,182	4,630
Selling and marketing		117	754	2,805	9,856	4,449	7,415
General and administrative	566	2,844	3,753	3,686	3,869	1,832	2,787
Total operating expenses	735	14,041	11,560	15,560	25,593	12,394	17,706
Interest and other income (expense), net		1,267	492	185	271	98	322
Net loss	$ (735)	$ (12,774)	$ (11,068)	$ (15,250)	$ (24,995)	$ (12,263)	$ (15,699)
Basic and diluted net loss per share	$ (10.10)	$ (20.14)	$ (11.95)	$ (12.43)	$ (14.38)	$ (7.26)	$ (8.28)
Shares used in computing basic	72,777	634,415	925,814	1,226,444	1,737,652	1,687,964	1,895,625

and diluted net loss per share	

(1) Includes non-cash charges for stock-based compensation expense of $191,000, $9,000 and $509,000 for the year ended December 31, 2004 and the six months ended June 30, 2004 and 2005, respectively.

	As of June 30, 2005		
	Actual	**Pro Forma**	**Pro Forma As Adjusted**
		(In thousands) (Unaudited)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 25,231	$ 25,231	$ 84,207
Working capital	23,306	23,306	82,282
Total assets	30,832	30,832	89,808
Capital leases, long-term	2,483	2,483	2,483
Convertible preferred stock	103,212		
Total stockholders equity (deficit)	(79,228)	23,984	82,960

The preceding table presents a summary of our unaudited consolidated balance sheet data as of June 30, 2005:

on an actual basis;

on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock into common stock upon the closing of this offering; and

on a pro forma as adjusted basis to give effect to the sale of 5,016,722 shares of our common stock in this offering at the initial public offering price of $12.00 per share, after deducting the underwriting discount and estimated offering expenses payable by us, and the sale of 416,666 shares of common stock to Incyte Corporation for cash proceeds of $5.0 million in connection with our exercise of a put right, at a purchase price equal to the initial public offering price of $12.00 per share.

Table of Contents

RISK FACTORS

You should carefully consider the risks described below before making a decision to buy our common stock. The risks and uncertainties described below are not the only ones we face. If any of the following risks actually occur, our business, financial condition and results of operations could be harmed. In that case, the trading price of our common stock could decline and you might lose all or part of your investment in our common stock. You should also refer to the other information set forth in this prospectus, including our consolidated financial statements and the related notes. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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 years ended December 31, 2002, 2003 and 2004 and the six months ended June 30, 2005, we had a net loss of $11.1 million, $15.3 million, $25.0 million and $15.7 million, respectively. From our inception in August 2000 through June 30, 2005, we had an accumulated deficit of approximately $80.5 million. To date, we have generated only minimal revenues, and we may never achieve revenues sufficient to offset expenses. We expect to devote substantially all of our resources to continue commercializing our existing product, Onco*type* DX, and to develop future products.

We expect to incur additional losses this year and 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 $7.1 million, $9.1 million and $10.0 million for the years ended December 31, 2002, 2003 and 2004, respectively, and $4.6 million for the six months ended June 30, 2005. We expect our research and development expense levels to remain high for the foreseeable future as we seek to enhance our existing product and develop new products. 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 for Oncotype DX, its commercial success could be compromised.

Onco*type* 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, 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. From commercialization of Onco*type* DX in January 2004 through June 30, 2005, approximately 90% of our revenues derived from the sale of Onco*type* DX have been paid by third-party payors. 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.

Table of Contents

Since each payor makes its own decision as to whether to establish a policy to reimburse for a test, seeking these approvals is a time-consuming and costly process. To date, we have secured policy-level reimbursement approval only from a limited number of third-party payors and have not secured any such approval from Medicare or any state Medicaid program. We cannot assure you that coverage for Onco*type* DX will be provided in the future by any third-party payors.

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 did 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.

In addition, in December 2004, the Northern California Medicare contractor with responsibility for processing and paying claims submitted by us announced that it would not provide coverage for Onco*type* DX for Medicare beneficiaries. It also indicated that there could be some questions concerning whether the hospital must bill Medicare or we can bill Medicare directly. Finally, it questioned which Medicare contractor has jurisdiction to determine coverage for Medicare claims for our test. Any determination that our test constitutes a hospital service as opposed to an outpatient procedure could result in lower payment rates in the event reimbursement is provided.

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. 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. 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.

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

Clinical laboratory services like Onco*type* DX are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as administered through the Center for Medicare/ Medicaid Services, as well as by applicable state laws. Diagnostic kits that are sold and distributed as products through interstate commerce are regulated as medical devices by the FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called home brew tests. Most home brew tests currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform home brew tests may be subject to regulation. We believe that Onco*type* DX is not a diagnostic kit and also believe that it is a home brew test. As a result, we believe Onco*type* DX is not subject to regulation under current 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 premarket review by the FDA.

In December 2004, the FDA, through the Office of In Vitro Diagnostic Devices, or OIVD, initiated a dialogue with us regarding the regulatory status of Onco*type* DX. We subsequently engaged in informal communications with the FDA regarding the status of our test. In early 2005, OIVD indicated that the FDA is considering whether our test may be subject to premarket review. We have not heard from the FDA since this communication. We cannot provide any assurance that the FDA will agree with our view on whether Onco*type* DX is subject to regulation or that FDA regulation, including review by the FDA before marketing, will not be required in the future for Onco*type* DX.

Table of Contents

If review by the FDA before marketing is required, we might have to stop selling our test until a review is completed and approval or clearance to market is obtained. In this case, the regulatory approval process could involve, among other things, successfully completing additional clinical trials and submitting a premarket clearance notice or filing a premarket approval application with the FDA. There is no assurance that the FDA would clear or approve our test. Ongoing compliance with FDA regulations would increase the cost, time and complexity of conducting our business. In addition, should any of the clinical laboratory device reagents, software or the tumor sample container used in or for our home brew test be affected by future regulatory actions, we could experience increased costs of testing or delays and limitations or unavailability of the reagents or software necessary to perform testing. If we are unable to obtain the reagents necessary to perform our test at all or on commercially reasonable terms, we would need to revise Onco*type* DX so that it would not require those reagents. Even if we were able to revise Onco*type* DX so that it would not require those reagents, we would then be required to re-validate our test before using it, which would be time-consuming and expensive.

If we were required to conduct additional clinical trials prior to marketing our products, those trials could lead to delays or failure to obtain necessary regulatory approvals and harm our ability to become profitable.

If the FDA decides to regulate our tests, it would require extensive premarket clinical testing prior to submitting a regulatory application for commercial sales. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our product development costs and delay product 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 approval for our products. 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 product, 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, 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, and we expect that we will be inspected within the next nine months. 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

Table of Contents

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 product, Oncotype DX, and we will need to generate sufficient revenues from this and other products to run our business.

For the foreseeable future, we expect to derive substantially all of our revenues from sales of one product, Onco*type* DX. We have only been selling this test since January 2004. We are in the early stages of research and development for other products that we may offer as well as for enhancements to our existing product. We are not currently able to estimate when we may be able to commercialize products 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 products or product enhancements, our revenues and our ability to achieve profitability would be impaired, and the market price of our common stock could decline.

We may experience limits on our revenues if only a small number of physicians decide to adopt 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, based on our clinical trial results, that 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 only a small number of patients decide 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 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, 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 tests to new treatments, then sales of our tests 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 tests. In return for the use of a third party s technology, we may agree to pay the licensor royalties based on sales of our products. Royalties are a component of cost of product revenues and impact the margin on our tests. 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.

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.

We do not have any issued patents. Our pending patent applications may not result in issued patents, and we cannot assure you that 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

Table of Contents

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.

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.

From time to time, we may receive notices of claims of infringement, misappropriation or misuse of other parties proprietary rights. 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 test or using technology that contains the allegedly infringing intellectual property, which could harm our business.

One of the genes in the Onco*type* DX 21-gene panel may be the subject of a patent, the rights of which are exclusively licensed by a subsidiary of Pfizer Inc. We have initiated discussions with Pfizer regarding a license of the patent but have not reached an agreement. If we are not able to negotiate a license on acceptable terms, and if our test is determined to infringe this patent, then we may be forced to develop an alternate method for performing our test. Revising our test may take more than a year and may require that we spend considerable amounts of money to develop a non-infringing gene panel and to validate our findings through a clinical study or studies. We may be forced to pay Pfizer royalties, damages and costs, or we may be prevented from selling our test altogether, which would greatly damage our business and operating results. Also, we are aware of other patents owned by Pfizer that relate to another gene in the Onco*type* DX 21-gene panel and are currently investigating whether any of the claims warrant a license. In addition, 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.

We also face competition from companies, such as Agendia B.V., that offer products or have conducted research to profile gene expression in breast cancer using fresh or frozen tissue. 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

Table of Contents

segment of Applera Corporation, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd, and Veridex LLC, a Johnson & Johnson company, as well as academic and research institutions.

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. 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 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. For example we have held discussions with the National Cancer Institute regarding conducting a large clinical study utilizing Onco*type* DX. 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 product development involves a lengthy and complex process, and we may be unable to commercialize any of the products we are currently developing.

We have multiple products under development and devote considerable resources to research and development. For example, we are currently conducting research on the application of our technology to predict recurrence and the therapeutic benefit of chemotherapy in colon, prostate, renal cell and lung cancers and melanoma. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of cancers, beyond breast cancer, 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. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes and as we attempt to transition to a company with more than one commercialized product. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including geneticists, licensed laboratory technicians, chemists 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

Table of Contents

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. We maintain key-person life insurance only on Randal Scott, our Chief Executive Officer, Joffre Baker, our Chief Scientific Officer, and Steven Shak, our Chief Medical Officer. We may discontinue this insurance in the future, it may not continue to be available on commercially reasonable terms or, if continued, it may prove inadequate to compensate us for the loss of these individuals services.

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

We do not have redundant laboratory facilities. We perform all of our diagnostic services 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 1993, the U.S. Congress passed federal self-referral prohibitions commonly known as the Stark Law, significantly restricting, regulating and changing healthcare companies 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.

We rely on a sole supplier for some of our laboratory instruments and may not be able to find replacements in the event our sole 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.

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

Since we only began the commercialization of Onco*type* DX in January 2004, we have limited experience in processing our test and even more limited experience in processing large volumes of tests. If demand for Onco*type* DX increases, we will be required 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 product 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 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.

Table of Contents

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 products 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 currently depend on one third-party distributor to sell Onco*type* DX in Israel. 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 products 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 additional capital to, among other things:

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

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

Table of Contents

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;

competing technological and market developments; and

changes in regulatory policies or laws that affect our operations.

If we raise additional 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 additional 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 additional 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 will be 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 of the Sarbanes-Oxley Act and other requirements will increase our costs and require additional management resources. We recently have been upgrading 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 new reporting requirements. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, 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 as of the date of our first Form 10-K for which compliance is required, 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.

Table of Contents

RISKS RELATED TO OUR COMMON STOCK

Our operating results may fluctuate, which could cause our stock price to decrease.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

- demand by physicians and patients for Onco*type* DX;
- reimbursement decisions by third-party payors and announcements of those decisions;
- clinical trial results and publication of results in peer-reviewed journals or the presentation at medical conferences;
- the inclusion or exclusion of our products in large clinical trials conducted by others;
- new or less expensive products and services or new technology introduced or offered by our competitors or us;
- the level of our development activity conducted for new products, and our success in commercializing these developments;
- the level of our spending on Onco*type* DX commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development;
- changes in the regulatory environment, including any announcement from the FDA regarding its decisions in regulating our activities;
- the impact of seasonality on our business;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel; and
- general market conditions.

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, the Nasdaq National Market in general, and the market for life science companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies.

If an active, liquid trading market for our common stock does not develop, you may not be able to sell your shares quickly or at or above the initial offering price.

Prior to this offering, there has not been a public market for our common stock. An active and liquid trading market for our common stock may not develop or be sustained following this offering. You may not be able to sell your shares quickly or at or above the initial offering price if trading in our stock is not active. The initial public offering price may not be indicative of prices that will prevail in the trading market. See Underwriting for more information regarding the factors that were considered in determining the initial public offering price.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock immediately after this offering. In other words, you are paying a price per share that substantially exceeds the value of our assets after subtracting our liabilities. At the initial public offering price of $12.00 per share and the pro forma net tangible book value of our common stock at June 30, 2005, your shares will be worth $8.59 less per share than you will pay in the offering.

Table of Contents

Further, investors participating in this offering will contribute approximately 35.6% of the total amount invested by stockholders since our inception but will only own approximately 20.7% of the total shares outstanding immediately after this offering. The exercise of outstanding options will result in further dilution of your investment. In addition, if we raise funds by issuing additional shares, the newly issued shares will further dilute your ownership interest.

We may allocate net proceeds from this offering in ways with which you may not agree.

Our management will have broad discretion in using the proceeds from this offering and may use the proceeds in ways with which you may disagree. Because we are not required to allocate the net proceeds from this offering to any specific investment or transaction, you cannot determine at this time the value or propriety of our application of the proceeds. Moreover, you will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use our proceeds. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment. As a result, you and other stockholders may not agree with our decisions.

Future sales of shares by our stockholders could cause the market price of our common stock to drop significantly, even if our business is doing well.

After this offering, we will have outstanding 24,367,432 shares of common stock based on the number of shares outstanding at August 31, 2005. This includes the 5,016,722 shares we are selling in this offering, which may be resold in the public market immediately, other than any shares sold to participants in our directed share program, which are subject to a 180-day lockup. The remaining 19,350,710 shares will become available for resale in the public market as shown in the chart below.

Number of Restricted Shares/% of Total Shares Outstanding Following Offering	Date of Availability for Resale into the Public Market
3,560,462/14.6%	180 days (subject to extension in specified circumstances) after the date of this prospectus due to the release of the lock-up agreement these stockholders have with the underwriters
15,790,248/64.8%	At some point after 180 days (subject to extension in specified circumstances) after the date of this prospectus, subject to vesting requirements and the requirements of Rule 144 (subject, in some cases, to volume limitations), Rule 144(k) or Rule 701

At any time and without public notice, the underwriters may in their sole discretion release all or some of the securities subject to the lock-up agreements. As restrictions on resale end, the market price of our stock could drop significantly if the holders of those shares sell them or are perceived by the market as intending to sell them. In addition, six months after this offering, the holders of 17,579,758 shares of common stock issued upon the conversion of our preferred stock may require us to file a registration statement covering those shares, which may also cause our stock price to decline. These declines in our stock price could occur even if our business is otherwise doing well.

If our principal stockholders, executive officers and directors choose to act together, they may be able to control our management and operations, which may prevent us from taking actions that may be favorable to you.

Our executive officers, directors and principal stockholders, and entities affiliated with them, will beneficially own in the aggregate approximately 46.1% of our common stock following this offering. To the extent our existing stockholders purchase additional shares, in this offering or otherwise, this ownership concentration would increase. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This

concentration of ownership

could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

We do not expect to pay dividends in the foreseeable future. As a result, you must rely on stock appreciation for any return on your investment.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

Anti-takeover provisions in our charter, bylaws and Delaware law may make it difficult for you to change our management and may also make a takeover difficult.

Our corporate documents and Delaware law contain provisions that limit the ability of stockholders to change our management and may also enable our management to resist a takeover. These provisions include limitations on persons authorized to call a special meeting of stockholders and advance notice procedures required for stockholders to make nominations of candidates for election as directors or to bring matters before an annual meeting of stockholders. These provisions might discourage, delay or prevent a change of control or in our management. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and cause us to take other corporate actions. In addition, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with our board of directors.

Table of Contents

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. The forward-looking statements are contained principally in the sections entitled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our expectation that, for the foreseeable future, substantially all of our revenues will be derived from Onco*type* DX;
- our expectation that our research and development expense levels will remain high as we seek to enhance Onco*type* DX and develop new products;
- our dependence on collaborative relationships;
- our compliance with federal, state and foreign regulatory requirements;
- the regulation of Onco*type* DX by the FDA;
- 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, such as insurance companies and health maintenance organizations, and government insurance programs, such as Medicare and Medicaid;
- increases in patient and physician demand resulting from our direct sales approach;
- plans for enhancements of our existing test, Onco*type* DX, to address different patient populations of breast cancer;
- plans for future products addressing multiple cancers, including colon, prostate, renal cell and lung cancers and melanoma;
- the outcome or success of clinical trials;
- the ability of genomics to change the diagnosis and treatment of diseases such as cancer and thereby provide significant economic benefits to the healthcare system;
- the capacity of our laboratory to process tests;
- the ability of our technology to screen increasing numbers of genes in tissue samples;
- our intellectual property and our strategies regarding filing additional patent applications to strengthen our intellectual property rights;
- our expected stock-based compensation expense in future periods;

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.

In some cases, you can identify forward-looking statements by terms such as may, might, will, objective, inten should, could, can, would, expect, believe, estimate, predict, potential, plan, or the negative of the expressions intended to identify forward-

Table of Contents

looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in this prospectus in greater detail under the heading Risk Factors. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. Unless required by U.S. federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This prospectus 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. 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.

Table of Contents

USE OF PROCEEDS

We expect that the net proceeds we will receive from the sale of the shares of common stock offered by us will be approximately $54.0 million, based on the initial public offering price of $12.00 per share, after deducting the underwriting discount and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we expect that our net proceeds will be approximately $62.3 million. We also will receive $5.0 million from our private sale of common stock to Incyte Corporation.

We currently expect to use our net proceeds from this offering as follows:

- approximately $25.0 million to build our commercial capabilities in selling and marketing related to Onco*type* DX;
- approximately $20.0 million to fund research and development programs for Onco*type* DX and in a variety of cancers;
- approximately $8.0 million for capital expenditures to expand facilities and laboratory operations capacity and for information systems infrastructure; and
- the balance for working capital and other general corporate purposes.

As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. 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. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

Pending use of the net proceeds as described above, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities.

DIVIDEND POLICY

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.

On September 8, 2005, our board of directors declared a conditional dividend of 791,210 shares of our common stock, which will be distributed upon the closing of this offering on a pro rata basis to all of our stockholders of record as of the date of this prospectus because the initial public offering price of our common stock is $11.40 or greater. This conditional dividend would not have been distributed if the initial public offering price of our common stock had been lower than $11.40. Our outstanding shares and stock options will be proportionately adjusted as a result of this dividend. Based on our outstanding stock options as of August 31, 2005, we will issue approximately 736,142 shares pursuant to this dividend, less an aggregate of 85 shares for which cash will be paid in lieu of fractional interests, and the number of shares underlying outstanding stock options will be increased by approximately 55,068 shares. The sum of the total number of shares issuable pursuant to the conditional dividend and the additional shares issuable upon exercise of our outstanding stock options as a result of the proportionate adjustments will equal 791,210 shares. See Description of Capital Stock Preferred Stock.

Table of Contents

CAPITALIZATION

The following table describes our cash, cash equivalents and capitalization as of June 30, 2005:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock into common stock upon the closing of this offering, and to give effect to the issuance of 791,210 shares of common stock pursuant to the conditional dividend; and
- on a pro forma as adjusted basis to give effect to the sale of 5,016,722 shares of common stock in this offering at the initial public offering price of $12.00 per share, after deducting the underwriting discount and estimated offering expenses payable by us, the sale of 416,666 shares of common stock to Incyte Corporation for cash proceeds of $5.0 million in connection with our exercise of a put right, at a purchase price equal to the initial public offering price of $12.00 per share.

You should read this table together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	June 30, 2005		
	Actual	Pro Forma	Pro Forma As Adjusted
	(In thousands, except share and per share data) (Unaudited)		
Cash and cash equivalents	$ 25,231	$ 25,231	$ 84,207
Capital leases, long-term	2,483	2,483	2,483
Convertible preferred stock, $0.0001 par value, issuable in series; 101,216,958 shares authorized, 48,480,819 shares issued and outstanding, actual; aggregate liquidation preference of $103,599 at June 30, 2005; 5,000,000 shares authorized, no shares issued or outstanding, pro forma; 5,000,000 shares authorized, no shares issued or outstanding, pro forma as adjusted	103,212		
Stockholders equity (deficit):			
Common stock, $0.0001 par value; 105,000,000 shares authorized, 1,932,921 shares issued and outstanding, actual; 100,000,000 shares authorized, 18,884,404 shares issued and outstanding, pro forma; 100,000,000 shares authorized, 24,317,792 shares issued and outstanding, pro forma as adjusted	1	2	2
Additional paid-in capital	5,085	108,296	167,272
Deferred stock-based compensation	(3,793)	(3,793)	(3,793)
Accumulated deficit	(80,521)	(80,521)	(80,521)
Total stockholders equity (deficit)	(79,228)	23,984	82,960

Total capitalization	$ 26,467	$ 26,467	$ 85,443

The actual, pro forma and pro forma as adjusted information set forth in the table:

- excludes 1,424,393 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2005, at a weighted average exercise price of $1.86 per share; and

- excludes 5,000,000 shares of common stock available for future issuance under our stock option plans following the date of this offering.

Table of Contents

DILUTION

Our pro forma net tangible book value as of June 30, 2005 was $24.0 million, or $1.27 per share of common stock. Pro forma net tangible book value per share represents the amount of our pro forma total tangible assets less total liabilities, divided by the pro forma number of shares of common stock outstanding, assuming the conversion of all shares of convertible preferred stock outstanding as of June 30, 2005 into shares of our common stock and the issuance of 791,210 shares of common stock pursuant to the conditional dividend. Pro forma net tangible book value dilution per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma net tangible book value per share of common stock immediately after completion of this offering on a pro forma as adjusted basis. After giving effect to the sale of the 5,016,722 shares of common stock by us at the initial public offering price of $12.00 per share, and after deducting the underwriting discount and estimated offering expenses payable by us, and our sale of 416,666 shares of common stock to Incyte Corporation for cash proceeds of $5.0 million in connection with our exercise of a put right, at a price per share equal to the initial public offering price, our pro forma net tangible book value as of June 30, 2005 would have been $83.0 million, or $3.41 per share of common stock. This represents an immediate increase in net tangible book value of $2.14 per share of common stock to existing common stockholders and an immediate dilution in pro forma net tangible book value of $8.59 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this per share dilution:

Initial public offering price per share		$ 12.00
Pro forma net tangible book value per share at June 30, 2005	$ 1.27	
Increase in pro forma net tangible book value per share attributable to new investors and the new investment by Incyte.	2.14	
Pro forma net tangible book value per share after this offering		3.41
Dilution in pro forma net tangible book value per share to new investors		$ 8.59

The following table summarizes as of June 30, 2005, on the pro forma basis described above, the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by existing and new investors purchasing shares of common stock in this offering, before deducting the underwriting discount and estimated offering expenses.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Average Price Per Share
Existing stockholders	18,819,233	77.6%	$ 104,027,660	61.5%	$ 5.53
New investors in this offering	5,016,722	20.7	60,200,664	35.6	12.00
New investment by Incyte	416,666	1.7	4,999,992	2.9	12.00
Total	24,252,621	100.0%	$ 169,228,316	100.0%	

The table above assumes no exercise of any outstanding stock options. As of June 30, 2005, there were 1,424,393 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $1.86 per share, and there were 5,000,000 shares of common stock available for future issuance under our

stock option plans following the date of this offering. To the extent that any of these options are exercised, there will be further dilution to new investors.

Table of Contents

SELECTED CONSOLIDATED 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 prospectus. The selected consolidated balance sheet data at December 31, 2003 and 2004 and the selected consolidated statements of operations data for each year ended December 31, 2002, 2003 and 2004 have been derived from our audited consolidated financial statements that are included elsewhere in this prospectus. The selected consolidated balance sheet data at December 31, 2000, 2001 and 2002 and the selected consolidated statements of operations data for the period from August 22, 2000 (inception) to December 31, 2000 and for the year ended December 31, 2001 have been derived from our audited consolidated financial statements not included in this prospectus. The selected consolidated balance sheet data at June 30, 2005 and the selected consolidated statements of operations data for the six months ended June 30, 2004 and 2005 are derived from our unaudited consolidated financial statements included in this prospectus. The unaudited consolidated financial statements include, in the opinion of management, all adjustments that management considers necessary for the fair presentation of the financial information set forth in those statements. Historical results are not necessarily indicative of the results to be expected in the future.

	Period from August 22, 2000 (inception) to Dec. 31, 2000	Year Ended December 31,			Six Months Ended June 30,	
		2001	2002	2003	2004	2004	2005
	(In thousands, except share and per share data)					(Unaudited)	
Consolidated Statements of Operations Data:							
Revenues:							
Product revenues	$	$	$	$	$ 227	$ 33	$ 1,585
Contract revenues				125	100		100
Total revenues				125	327	33	1,685
Operating expenses(1):							
Cost of product revenues					1,828	931	2,874
Research and development	169	11,080	7,053	9,069	10,040	5,182	4,630
Selling and marketing		117	754	2,805	9,856	4,449	7,415
General and administrative	566	2,844	3,753	3,686	3,869	1,832	2,787

Total operating expenses	735	14,041	11,560	15,560	25,593	12,394	17,706
Loss from operations	(735)	(14,041)	(11,560)	(15,435)	(25,266)	(12,361)	(16,021)
Interest and other income (expense), net		1,267	492	185	271	98	322
Net loss	$ (735)	$ (12,774)	$ (11,068)	$ (15,250)	$ (24,995)	$ (12,263)	$ (15,699)
Basic and diluted net loss per share	$ (10.10)	$ (20.14)	$ (11.95)	$ (12.43)	$ (14.38)	$ (7.26)	$ (8.28)
Shares used in computing basic and diluted net loss per share	72,777	634,415	925,814	1,226,444	1,737,652	1,687,964	1,895,625

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

	Period from August 22, 2000 (inception) to Dec. 31, 2000	Year Ended December 31,				Six Months Ended June 30,	
		2001	2002	2003	2004	2004	2005
		(In thousands)				(Unaudited)	
Cost of product revenues	$	$	$	$	$ 5	$ 1	$ 21
Research and development					42	6	166
Selling and marketing					38	1	210
General and administrative					106	1	112
	$	$	$	$	$ 191	$ 9	$ 509

Table of Contents

	At December 31,					At June 30,
	2000	2001	2002	2003	2004	2005
	(In thousands)					(Unaudited)
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 7,503	$ 28,678	$ 25,318	$ 11,062	$ 38,275	$ 25,231
Working capital	7,173	26,724	25,165	10,046	36,771	23,306
Total assets	7,617	30,408	27,376	13,096	41,538	30,832
Capital leases, short-term			163	161		777
Capital leases, long-term			150			2,483
Convertible preferred stock	7,917	41,783	51,073	51,064	103,212	103,212
Accumulated deficit	(735)	(13,509)	(24,577)	(39,827)	(64,822)	(80,521)
Total stockholders equity (deficit)	(731)	(13,482)	(24,502)	(39,547)	(64,154)	(79,228)

Table of Contents

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements based upon current expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Risk Factors, Information Regarding Forward-looking Statements and elsewhere in this prospectus.

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 within 10 years of diagnosis 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. As of June 30, 2005, Onco*type* DX has been ordered by over 1,400 physicians throughout the United States. 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 2005, we have experienced a significant increase in demand for Onco*type* DX. In the year ended December 31, 2004 and the six months ended June 30, 2005, 500 and 3,000 tests, respectively, were ordered by treating physicians. We believe this increase in demand resulted from the publication of our validation study in *The New England Journal of Medicine* and the presentation of an additional study at the San Antonio Breast Cancer Symposium, both of which occurred in December 2004. However, this increased demand for our product is not necessarily indicative of future growth rates, and we cannot assure you that this level of increased demand can be sustained. Moreover, we believe that each year we may experience decreased demand for our tests in the summer months of July and August, which may be attributed to physicians, surgeons and patients scheduling vacations during this time. As of June 30, 2005, our laboratory had the capacity to process up to 2,500 tests per quarter, and our current expansion plan contemplates that we will have capacity to process up to 4,000 tests per quarter by the end of 2005.

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 testing services, when covered, are paid under various methodologies, including prospective payment systems and fee schedules. Reimbursement from payors depends upon whether a service is covered under the patient s policy and if payment practices for the service 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 an insurer on contract terms or establish a policy for payment of Onco*type* DX, we expect to 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 August 2005, several regional payors, including Harvard Pilgrim Health Care, Inc. and Highmark Blue Cross Blue Shield, had issued policies supporting reimbursement for our test. In addition, Kaiser Foundation Health Plan, Inc. has entered into a national clinical laboratory services agreement to reimburse us for Onco*type* DX tests performed for their patients. Where policies are not in place, we pursue case-by-case reimbursement. We believe that as much as 20% of our future revenues may be derived from tests billed to Medicare. We are working with many payors, including Medicare, to establish policy-level reimbursement which, if in place, will allow us to recognize revenues upon submitting an invoice. We do not expect to recognize the majority of revenues in this manner until 2007, at the earliest.

29

Table of Contents

Since our inception, we have generated significant net losses. As of June 30, 2005, we had an accumulated deficit of $80.5 million. We incurred net losses of $11.1 million, $15.3 million and $25.0 million in the years ended December 31, 2002, 2003 and 2004, respectively, and $15.7 million in the six months ended June 30, 2005. We expect our net losses to continue for at least the next several years. We anticipate that a substantial portion of our capital resources and efforts will be focused on research and development, both to develop additional tests for breast cancer and to develop products for other cancers, scale up our commercial organization, and 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 processed 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 and operate in one industry segment. Our product revenues are derived solely from the sale of Onco*type* DX. Payors are generally 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. All product revenues recognized to date reflect cash collections. Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recorded on an accrual basis upon completion of the contractual obligation.

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. On the other hand, 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 from our inception in August 2000 through December 31, 2003 were $27.4 million, and substantially all of these expenses were focused on the research and development of Onco*type* DX, which we launched in January 2004. During this time, Onco*type* DX was the only product under development. Research and development expenses represent costs incurred both to develop our technology and to carry out our clinical studies to validate our multi-gene tests. Most of the costs incurred prior to 2003 were to develop our technology. During the years ended December 31, 2003 and 2004 and the six months ended June 30, 2005:

- costs incurred for salaries and benefits were $4.2 million, $4.7 million and $2.7 million;
- costs paid to third party clinical collaborators, including contract services, were $890,000, $1.8 million and $34,000;
- costs allocated to overhead and facilities were $1.3 million, $990,000 and $679,000;
- depreciation costs for equipment were $576,000, $413,000 and $181,000;
- costs for materials to conduct gene assays in clinical research and development studies were $918,000, $964,000 and $639,000;
- license and technology rights were $991,000, $1.0 million and $328,000; and

all other costs were $167,000, $143,000 and $72,000.

We charge all research and development expenses to operations as they are incurred. All potential future product programs outside of breast cancer are in the clinical research phase, and the earliest we expect

Table of Contents

another cancer program to reach the development stage is 2006. However, the expected time frame that a product related to 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.

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.

Our significant accounting policies are described in Note 1 to our consolidated financial statements included elsewhere in this prospectus. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our financial statements.

Revenue Recognition

We have generated limited revenues since our inception. Product revenues for our first product, Onco*type* DX, were minimal from the commercial launch in January 2004 through June 30, 2005, and were recognized on a cash basis. To date, we have recognized all of our product revenues on a cash basis because we have limited collection experience and a limited number of contracts. In accordance with our policy, revenues for tests performed will be recognized on an accrual basis when the related costs are incurred, provided there is a contract or coverage policy in place and the following criteria are met:

- persuasive evidence that an arrangement exists;
- delivery has occurred or services rendered;
- the fee is fixed and determinable; and
- collectibility is reasonably assured.

Determination of the last two criteria will be based on management s judgments regarding the nature of the fee charged for products or services delivered and the collectibility of those fees.

Table of Contents

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. 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.

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.

Deferred Stock-based Compensation Expense

Stock-based compensation expense, which is a non-cash charge, results from stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the fair value of the underlying common stock. We recognize stock-based compensation expense on a straight-line basis over the vesting period of the underlying option, which is generally four years. The amount of stock-based compensation expense expected to be amortized in future periods may decrease if unvested options for which deferred stock-based compensation expense has been recorded are subsequently cancelled or may increase if future option grants are made with exercise prices below the deemed fair value of the common stock on the date of measurement.

During the period from January 1, 2004 through June 30, 2005, we granted options to employees to purchase a total of 1,066,565 shares of common stock at exercise prices ranging from $1.38 per share to $3.30 per share. We did not obtain contemporaneous valuations from an independent valuation specialist in connection with these grants. Instead, we relied on our board of directors, the members of which we believe have extensive experience in the life science industry and a majority of which is comprised of non-employee directors, to determine a reasonable estimate of the then-current value of our common stock. Given the absence of an active market for our common stock and resulting lack of liquidity in 2004 and the six months ended June 30, 2005, our board of directors determined the estimated fair value of our common stock on the date of grant based on several factors, including the sales prices and liquidation preferences of our preferred stock, progress and milestones achieved in our business, our financial condition, equity market conditions, trading ranges of comparable public companies and the likelihood of achieving a liquidity event such as an initial public offering or a sale of the company given prevailing market conditions.

In connection with our proposed initial public offering, we have reassessed the fair value of our common stock. In determining the reassessed fair value per share of the common stock as of each grant date, the factors identified in the preceding paragraph were taken into account. We also considered other material factors and business developments, including the following:

- we commercially launched Onco*type* DX in January 2004;
- we conducted studies in 2004 with the NSABP to test additional attributes of Onco*type* DX;
- in the summer of 2004 and later in September 2004, the results of these studies demonstrated that Onco*type* DX predicts the likelihood of breast cancer recurrence and chemotherapy benefit;
- in October 2004, *The New England Journal of Medicine* accepted our validation study for publication and published an online version of the results in December 2004;
- the results of several of our studies were presented at the annual San Antonio Breast Cancer Conference in December 2004;

in December 2004, the FDA, through the Office of In Vitro Diagnostic Devices, initiated a dialogue with us regarding the regulatory status of Onco*type* DX;

Table of Contents

in December 2004, the local Medicare contractor in Northern California indicated that it would not provide coverage for Onco*type*DX;

in early 2005, the Medical Advisory Panel of the Blue Cross and Blue Shield Association concluded that Onco*type* DX did not meet the panel s technology criteria for clinical effectiveness and appropriateness;

beginning in early 2005, we began entering into contracts or establishing policies with third-party payors to reimburse us for our tests;

in the first quarter of 2005, our board of directors authorized us to initiate the process of preparing for an initial public offering; and

the market for new public offerings made by life science companies in 2005 and the six months ended June 30, 2005 was highly volatile.

In reassessing the value of our common stock, we used a straight-line approach because we determined that no single event supported incremental movement in underlying value. Further, we believe this approach is consistent with valuation methodologies applied by other similar life science companies pursuing an initial public offering. Based upon the reassessment process, we determined that the reassessed fair value of the options granted from January 1, 2004 through June 30, 2005 ranged from $1.95 to $11.25 per share. Accordingly, deferred stock-based compensation of $3.6 million was recorded during the year ended December 31, 2004 and $846,000 was recorded during the six months ended June 30, 2005 in accordance with Accounting Principles Board, or APB, Opinion No. 25. The deferred stock-based compensation will be amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. For the year ended December 31, 2004, we recorded employee stock-based compensation expense of $191,000, $5,000 of which was allocated to cost of product revenues and $186,000 of which was allocated to other operating expenses. We expect deferred stock-based compensation expense under APB Opinion No. 25 to be $372,000, $1.1 million, $1.1 million and $1.0 million for the last four months of 2005 and for the years ending December 31, 2006, 2007 and 2008 (and thereafter), respectively, before consideration of the impact of the recent changes in accounting pronouncements for stock options.

The information regarding net loss as required by Statement of Financial Accounting Standards, or SFAS, No. 123, presented in Note 1 to our consolidated financial statements, has been determined as if we had accounted for our employee stock options under the fair value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the impact of future years vesting.

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. All clinical collaborators enter into agreements with us which specify work content and payment terms.

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 in which the relevant payment is made. However, either party may terminate the agreement upon 30 days prior written notice. If this collaborative arrangement were not cancelable, a liability for the entire stream of remaining payments of $2.5 million would be recorded, payments would be made annually and expense would be recognized ratably through 2011.

Results of Operations

Six Months Ended June 30, 2005 and 2004

Revenues. Revenues were $1.7 million for the six months ended June 30, 2005, as compared to $33,000 for the comparable period in 2004. All revenues in 2004 were product revenues from our first product, Onco*type* DX, which was launched in January 2004. During 2005, product revenues were $1.6

33

Table of Contents

million and contract revenues were $100,000. First cash collections for Onco*type* DX were received during the second quarter of 2004. These revenues were recognized upon cash receipt.

Cost of Product Revenues. For the six months ended June 30, 2005, cost of product revenues was $2.9 million, consisting of tissue sample processing costs of $2.6 million for tests performed during the period and license fees of $292,000. For the six months ended June 30, 2004, cost of product revenues was $931,000, consisting of tissue sample processing costs of $571,000 and license fees of $360,000. All costs for tissue sample processing were recorded in the period in which the test was processed, regardless of whether revenue was recognized with respect to that test. Recorded costs for Onco*type* DX include direct material costs, direct labor costs, equipment costs and other infrastructure costs. License fees were recorded in cost of product revenues for contractual obligations and royalties due on product revenues. The decrease in license fees resulted from non-recurring payments owing due to the commercialization of our test in January 2004. Costs of product revenues will increase as an absolute number as the volume of tests processed increases.

Research and Development Expenses. Research and development expenses were $4.6 million for the six months ended June 30, 2005, a decrease from $5.2 million for the comparable period of 2004. This decrease is a result of spending $1.1 million less on clinical programs in 2005 as compared to 2004 and a $192,000 reduction in license agreement costs. These decreases were partially offset by higher personnel costs in research and development of $521,000 and increases in laboratory supplies of $163,000. We expect research and development expenses to increase as we work to develop additional tests for breast cancer and for other cancers.

Selling and Marketing Expenses. Selling and marketing expenses increased to $7.4 million for the six months ended June 30, 2005, from $4.4 million for the comparable period in 2004. The increase was due in part to personnel costs of $1.8 million and travel and entertainment costs of $532,000 associated with the growth of the commercial field sales team compared to limited spending in this area in the first half of 2004 when Onco*type* DX was launched. Additionally, promotional spending for Onco*type* DX was $505,000 higher for the six months ended June 30, 2005 than for the comparable period in 2004. We expect selling and marketing expenses to increase as a result of continued growth in our sales infrastructure to support growth in our product revenues and billings and as we incur a full year of costs for the field sales personnel hired in late 2004 and as we hire additional sales personnel.

General and Administrative Expenses. General and administrative expenses totaled $2.8 million for the six months ended June 30, 2005, as compared to $1.8 million for the comparable period in 2004. This increase was due in part to increases in personnel costs of $596,000, legal costs of $157,000 and billing and collections costs of $160,000. We expect general and administrative expenses to increase after this offering as a result of the need to hire additional administrative personnel and due to higher legal, accounting and related expenses associated with being a public company.

Interest Income and Other Income/ Expense. Interest income was $393,000 for the six months ended June 30, 2005, compared with $121,000 in the comparable period in 2004. This increase was due to higher average cash balances from preferred stock financings and higher interest rates during the six months ended June 30, 2005. Other income during the six months ended June 30, 2005 was $1,000 as compared to $20,000 of expense in the comparable period of 2004.

Interest Expense. Interest expense was $72,000 in the six months ended June 30, 2005, compared with $3,000 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 period. We expect interest expense to increase as we make interest payments on borrowings under our equipment loan and make further draws throughout the remainder of 2005.

Years Ended December 31, 2004 and 2003

Revenues. Revenues were $327,000 for the year ended December 31, 2004, as compared to $125,000 for the comparable period in 2003. Product revenues for the year ended December 31, 2004 were $227,000, as

compared to zero in the comparable period in 2003. Product revenues were all recognized upon cash receipt. Contract revenues were $100,000 for the year ended December 31, 2004, down from $125,000 in the comparable period in 2003. Contract revenues in both periods were for studies assessing our gene expression technology.

Cost of Product Revenues. 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 related to the launch of Onco*type* DX and license fees of $477,000. During the year ended December 31, 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 that year 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. No cost of product revenues were recorded in the year ended December 31, 2003 because we had not commercialized Onco*type* DX.

Research and Development Expenses. Research and development expenses increased to $10.0 million for the year ended December 31, 2004, from $9.1 million for the comparable period in 2003. The increase in research and development expenses is primarily due to $944,000 in increased costs for clinical development programs studying distant survival and chemotherapy benefits in early stage breast cancer patients and increased personnel costs of $476,000, partially offset by a decrease of $518,000 in facilities, depreciation and other general expenses.

Selling and Marketing Expenses. Selling and marketing expenses increased to $9.9 million for the year ended December 31, 2004, from $2.8 million for the comparable period in 2003. The $7.1 million increase primarily reflects an increase of $2.6 million for higher promotional, education and tradeshow expenses, an increase of $2.8 million in personnel related costs, mostly to establish a domestic field sales organization, and $831,000 in higher travel expenses associated with field sales personnel, as well as costs of $405,000 for patient advocacy programs. For the year ended December 31, 2003, selling and marketing expenses were primarily for personnel related costs and market research.

General and Administrative Expenses. General and administrative expenses of $3.9 million for the year ended December 31, 2004 were slightly higher than the $3.7 million for the comparable period in 2003. The increase in general and administrative expenses reflects an increase of $352,000 in recruiting and relocation costs, an increase of $250,000 in legal costs and miscellaneous increases in personnel and consulting related costs. These higher costs are offset in part by a $493,000 decrease in costs related to information technology support.

Interest Income and Other Income/Expense. Interest income was $295,000 for the year ended December 31, 2004, compared with $199,000 in the comparable period in 2003. This $96,000 increase was due to higher average cash balances from preferred stock financings and higher interest rates during the year ended December 31, 2004. Other expense was $20,000 for the year ended December 31, 2004, and was zero for the comparable period in 2003.

Interest Expense. Interest expense is comprised of the interest on deferral of contractual payments under a collaboration agreement. Interest expense decreased to $4,000 for the year ended December 31, 2004, from $14,000 in the comparable period in 2003 due to completing payments under the payment schedule. The final payment under this agreement was made in October 2004.

Years Ended December 31, 2003 and 2002

Revenues. Contract revenues of $125,000 were recorded for the year ended December 31, 2003, related to two studies assessing our gene expression technology, both of which were completed in 2003. There were no revenues for the year ended December 31, 2002.

Research and Development Expenses. Research and development expenses were $9.1 million for the year ended December 31, 2003, up from $7.1 million for the comparable period in 2002. The increase of $2.0 million was primarily due to $850,000 of higher personnel related costs, an increase in the general

overhead allocation to our research and development department of $755,000 and $699,000 in higher costs associated with our clinical development programs. These increases in 2003 were partially offset by a reduction of $496,000 in payments to clinical collaborators.

Selling and Marketing Expenses. Selling and marketing expenses were $2.8 million for the year ended December 31, 2003, up from $754,000 for the comparable period in 2002. The increase of $2.0 million reflects primarily increased costs of $1.0 million for market research, promotion and tradeshow costs in preparation for the January 2004 launch of Onco*type* DX and other patient advocacy programs and increases of $742,000 in personnel related costs as we began to establish our domestic field sales organization. Selling and marketing expenses for the year ended December 31, 2002, were primarily related to personnel, consulting and market research services.

General and Administrative Expenses. General and administrative expenses decreased to $3.7 million for the year ended December 31, 2003, from $3.8 million for the comparable period in 2002.

Interest Income. Interest income decreased to $199,000 for the year ended December 31, 2003, from $502,000 for the comparable period in 2002. This decrease was due to significantly lower average cash and investment balances as well as lower interest rates in calendar year 2003 as compared to calendar year 2002.

Interest Expense. Interest expense was $14,000 for the year ended December 31, 2003, as compared to $13,000 for the year ended December 31, 2002. All interest expense amounts related to deferred contractual payments under a collaboration agreement.

Liquidity and Capital Resources

Since our inception in August 2000, we have incurred significant losses and, as of June 30, 2005, we had an accumulated deficit of approximately $80.5 million. We have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. 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, substantially all of our operations have been financed through the sale of our preferred stock. Through June 30, 2005, we had received net proceeds of $103.2 million from the sale of preferred stock and $425,000 from the issuance of common stock to employees, consultants and directors in connection with the exercise of stock options. We also financed our operations, purchases of equipment and leasehold improvements through loans. As of December 31, 2004, we had cash and cash equivalents of $38.3 million and no debt, and, at June 30, 2005, we had cash and cash equivalents of $25.2 million and debt under our equipment loan of $3.3 million.

Cash Flows

As of June 30, 2005, we had $25.2 million in cash and cash equivalents, compared to $38.3 million at December 31, 2004. This decrease was due primarily to cash used in operating activities of $14.8 million, initial public offering costs of $1.1 million and purchases of property and equipment of $1.6 million, offset partially by proceeds from our equipment loan of $3.3 million and the issuance of common stock of $58,000.

Net cash used in operating activities was $14.8 million for the six months ended June 30, 2005, compared to $11.4 million for the six months ended June 30, 2004. The increase in cash used of $3.4 million was primarily due to an increase in selling and marketing expenses of $3.0 million and higher lab processing costs of $1.9 million, offset by cash collected from customers of $1.6 million.

Net cash used in operating activities was $23.1 million, $13.5 million and $12.3 million for the years ended December 31, 2004, 2003 and 2002, respectively. Net cash used in operating activities for these periods consisted primarily of our net loss, partially offset by depreciation of property and equipment.

Table of Contents

Net cash used in investing activities was $1.6 million for the six months ended June 30, 2005, compared to $797,000 for the six months ended June 30, 2004. This cash was used to acquire property and equipment and for leasehold improvements.

Net cash used in investing activities was $1.8 million, $739,000 and $631,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Our investing activities for these periods consisted primarily of purchases of property and equipment. We expect amounts used in investing activities to increase in 2005 and beyond as we expand research and development activities and capacity in our commercial laboratory.

Net cash provided by financing activities during the six months ended June 30, 2005 was $3.3 million, compared to $29.9 million for the six months ended June 30, 2004. Substantially all amounts in the 2004 period represented proceeds from our sale of series E preferred stock. Amounts in the six months ended June 30, 2005 consisted of proceeds from our equipment loan of $3.3 million and the issuance of $58,000 of common stock.

Net cash provided by financing activities was $52.1 million, $27,000 and $9.6 million for the years ended December 31, 2004, 2003 and 2002, respectively. Financing activities consisted primarily of the sale of our preferred stock for the years ended December 31, 2002 and 2004 and the sale of our common stock in the year ended December 31, 2003.

Contractual Obligations

As of December 31, 2004, 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)		
Operating lease obligations	$ 944	$ 813	$ 131	$	$

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. A payment of $150,000 was made in 2005. We are required to make additional payments of $300,000 in each of 2006 and 2007, and $475,000 in each of 2008 through 2011. However, either party may terminate the agreement upon 30 days prior written notice.

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 cannot prepay any amounts owed until 2006, at which point we can 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 August 31, 2005, borrowings under this arrangement were $3.7 million at an annual interest rate of 10.23%, 10.30%, 10.49%, 10.56% or 10.65%, depending on the applicable note. As of August 31, 2005, we are required to make payments under this arrangement of $417,000 in 2005, $1.3 million in 2006, $1.3 million in 2007, $1.1 million in 2008 and $275,000 in 2009. We expect to request to borrow additional amounts under this arrangement.

We currently sublease approximately 25,000 square feet of laboratory and office space under a sublease that expires in February 2006. In September 2005, we entered into a lease directly with the facility owner that has a term of six years. When our existing sublease expires in February 2006, the new lease will apply to the existing 25,000 square feet of laboratory and office space we currently occupy. Under the new lease, we also lease approximately 23,000 square feet of additional space which we expect to first occupy in March 2006. If we first occupy space under

this new lease in March 2006, we will be required to make aggregate rent payments of $460,000 in 2006, $730,000 in 2007, $753,000 in 2008, $779,000 in 2009, $799,000 in 2010, $827,000 in 2011 and $139,000 in 2012.

Table of Contents

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, which we expect to fund in part with the proceeds of this offering. It may take several years to move any one of a number of product candidates in clinical research through the development phase and validation phase to commercialization. We expect that the remainder of the net proceeds and our existing 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 the processing of tests outside the United States or reduction of debt obligations. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the progress of our product development, regulatory requirements, commercialization efforts, the amount of cash used by operations and progress in reimbursement. We expect that we will receive limited payments for Onco*type* DX test 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 test billings.

We currently anticipate that our cash and cash equivalents, together with proceeds from this offering, collections for Onco*type* DX and amounts available under our equipment credit facility, will be sufficient to fund our operations 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 products for breast cancer;
- the rate of progress and cost of research and development activities associated with products in the research phase focused on cancer, 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.

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. 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.

Income Taxes

Since inception, we have incurred operating losses and, accordingly, have not recorded a provision for income taxes for any of the periods presented. As of December 31, 2004, we had net operating loss carryforwards for federal and state income tax purposes of $60.2 million and $57.8 million, respectively. We also had federal and state research and development tax credit carryforwards of $855,000 and $569,000, respectively. If not utilized, the federal net operating loss and tax credit carryforwards will expire beginning in 2021. Utilization of net operating loss and credit carryforwards may be subject to a substantial annual limitation due to restrictions contained in the Internal Revenue Code that are applicable if we experience an ownership change that may occur, for example, as a result of this offering being aggregated with certain other sales of our stock before or after this offering. If not utilized, the state net operating loss carryforward will expire beginning in 2013. The annual limitation may result in the expiration of our net operating loss and tax credit carryforwards before they can be used.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 123(R), *Share-Based Payment*, which is a revision of SFAS 123, *Accounting for Stock-Based Compensation.* SFAS 123(R) is effective for public companies for the first interim or annual period beginning after June 15, 2005, supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FAS 95, *Statement of Cash Flows.* Generally, the approach in SFAS 123(R) is similar to the approach described in FAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The new standard will be effective for us beginning January 1, 2006. Under SFAS 123(R), we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive adoption option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options at the beginning of the first quarter of adoption of SFAS 123(R), while the retroactive method would record compensation expense for all unvested stock options beginning with the first period restated.

Management is evaluating the requirements of SFAS 123(R) and expects that its adoption may have a material impact on our consolidated results of operations and earnings per share. Management has not yet determined the method of adoption or the effect of adopting SFAS 123(R), and has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123.

Qualitative and Quantitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments through a variety of securities, including commercial paper, money market funds and corporate debt securities. Our cash and cash equivalents through December 31, 2004, included liquid money market accounts.

Table of Contents

BUSINESS

Company 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. 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. Approximately half of the 230,000 patients expected to be diagnosed with breast cancer in the United States in 2005 are predicted to be early stage 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 response to chemotherapy. 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. In 2004, over 500 tests were ordered by treating physicians. In December 2004, our validation study was published in *The New England Journal of Medicine* and the results of additional clinical trials were presented at the San Antonio Breast Cancer Conference. In the six months ended June 30, 2005, over 3,000 tests were ordered by treating physicians. As of June 30, 2005, Onco*type* DX has been ordered by over 1,400 physicians throughout the United States.

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 2005, approximately 1.4 million people in the United States are 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 truly 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.

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.

Table of Contents

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 respond to 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 and, consequently, design an individualized treatment plan.

Improved Economics of Cancer Care. We believe that improving the quality of treatment decisions can result in significant economic benefits. In early stage breast cancer, our data shows that many patients

Table of Contents

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 may cost in excess of $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.

Business Strategy

Our goal is to improve the quality of treatment decisions for cancer patients by providing individualized information to patients and their physicians through the genomic analysis of tumor biopsies. Key elements of our strategy include:

Deliver High-value Genomic-based Diagnostics. We believe that treatment decisions are currently being made with little understanding of the molecular profile of each tumor and that economic inefficiencies result in the healthcare system when crucial and expensive treatment decisions are made based on inadequate and often subjective information. Our strategy is to identify treatment decisions that can benefit from, and be guided by, the patient s individual genomic information. We are focused on developing high-value tests that address these treatment decisions, with the goal of making our genomic-based tests a standard of care. Our value lies in our ability to deliver individualized information during the crucial period of time after diagnosis but prior to the decision to undergo a specific cancer treatment.

Achieve Broad-based Adoption and Reimbursement. We intend to continue to build a strong sales, marketing and reimbursement effort by interacting directly with medical and surgical oncologists, pathologists and payors. Because oncology is a concentrated specialty, we believe that a focused marketing organization and specialized sales force can effectively serve the oncology community and provide us with a competitive advantage. We believe our direct sales approach, coupled with our plans to conduct multiple clinical studies with results published in peer-reviewed journals, will increase patient and physician demand and increase the number of favorable reimbursement coverage decisions by payors.

Enhance Existing Products and Technologies. Our goal is to enhance our marketed products by validating additional individualized patient information to improve treatment planning. We also intend to deliver added value by expanding the clinical categories of patients we can address within a cancer population. For example, we plan to expand our breast cancer product to address late-stage breast cancer patients as well as questions about the responsiveness of an individual tumor to therapeutic agents such as aromatase inhibitors and taxanes. We believe that continuous innovation can sustain a competitive advantage by delivering more information to physicians in comparison with new competitive products entering the market.

Apply Our Clinical Development Platform to Other Cancers. We intend to use our clinical development platform to address multiple cancers for which quantitative molecular pathology could improve the assessment of the risk of disease progression and the prediction of response to therapy. In the next several years, we plan to expand our focus beyond breast cancer, potentially including colon, prostate, renal cell and lung cancers and melanoma. We designed our clinical development platform to enable us to conduct clinical studies with clinical study groups and opinion leaders using archived biopsy specimens with years of associated patient data to correlate genomic information to clinical outcomes. This approach allowed us to research, develop, validate and commercialize Onco*type* DX in three years.

Our Product: Onco*type* DX

Onco*type* DX uses quantitative molecular pathology to improve cancer treatment decisions. We offer Onco*type* DX as a clinical laboratory service, 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

Table of Contents

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 response to 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 chemotherapy benefit, and we are undertaking further studies to support this finding.

Oncotype DX for Breast Cancer

Approximately 230,000 new cases of breast cancer are expected to be diagnosed in the United States in 2005. 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 response to chemotherapy and some are subjective, a large percentage of early stage breast cancer patients are classified as high risk. As a consequence, the use of chemotherapy has become standard practice in 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.

Table of Contents

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 accredited under CLIA and 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 0-100 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 a 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 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 0-100.

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

Table of Contents

2004 and further detailed results were presented at the annual meeting of the American Society of Clinical Oncology, or ASCO, in May 2005. 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 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, response to tamoxifen, or both. This study s conclusions were reported at the San Antonio Breast Cancer Conference in December 2004 and further detailed results were presented at ASCO s annual meeting in May 2005. 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 response to tamoxifen. 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 response to tamoxifen. 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 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

Table of Contents

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. One such study, which was published in *The American Journal of Managed Care*, 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:

Clinical Research 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 1,000 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.

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

49

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. 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. Multiple clinical studies are also useful for driving adoption and reimbursement by physicians and payors.

Our Product Pipeline

Over 550,000 treatment decisions are expected to be made in the United States in 2005 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.

Table of Contents

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	2005 Estimated Treatment Decisions in the United States	Anticipated Product Attributes	Product Stage
Onco*type* DX	N-, ER+	125,000	Recurrence Response to chemotherapy	Commercial
			Response to chemotherapy or other therapeutic regimens	Product Expansion
	N+	65,000	Recurrence Response to chemotherapy or other therapeutic regimens	Product Expansion
Onco*type* DX Second Generation	N-, ER+ and N+	190,000[1]	Enhanced recurrence Enhanced response to chemotherapy	Clinical Research
New Products	N-, ER-	30,000	Response to taxanes[2] Response to chemotherapy Recurrence	Clinical Research
	N+	65,000[3]	Response to taxanes Response to chemotherapy	Clinical Research
	N-, ER+	125,000[4]	Response to taxanes	Clinical Research

(1) Represents the sum of the 125,000 estimated treatment decisions in 2005 for N-, ER+ patients and the 65,000 estimated treatment decisions in 2005 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 65,000 treatment decisions listed above.

(4) This figure is the same as the 125,000 treatment decisions listed above.

Oncotype DX

We are conducting clinical studies with Onco*type* DX to expand the market and improve certain product features. Approximately 65,000 patients are expected to be diagnosed in the United States in 2005 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* DX for this patient population. Additional studies are in the planning stage to investigate whether Onco*type* DX predicts the likelihood of recurrence in patients who use other hormonal therapies instead of tamoxifen. Additionally, we believe that individual gene scores which contribute 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 response to tamoxifen based on our studies of the NSABP Study B-14 population.

Second Generation Oncotype DX

We are in the clinical research phase to investigate 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 response to chemotherapy.

Recurrence and Response Test for N-, ER- Breast Cancer

We are in the clinical research phase to develop a product to predict the likelihood of recurrence and response to chemotherapy in N-, ER- breast cancer patients. This population is expected to represent approximately 30,000 patients in the United States in 2005. 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 Response Test

We are also in the clinical research phase to develop a product to predict the response of patients to taxanes. 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 65,000 N+ breast cancer patients as well as N-, ER-patients at high risk and N- patients at high risk in the United States in 2005. We have developed a number of hypotheses and selected a gene panel to investigate this product opportunity further.

Table of Contents

Product Development Opportunities in Other Cancers

The following table describes our new products in development for cancers other than breast cancer:

Product Opportunity	2005 Estimated Total Incidence in the United States	2005 Estimated Addressable Population	Anticipated Product Attributes	Product Stage
Colon Cancer	120,000	65,000	Recurrence	Clinical
			Prediction of drug response	Research
Prostate Cancer	250,000	195,000	Progression	Clinical
			Recurrence	Research
Renal Cell Cancer	40,000	25,000	Recurrence	Clinical
			Prediction of drug response	Research
Non-small Cell Lung Cancer	155,000	25,000	Recurrence	Clinical
			Prediction of drug response	Research
Melanoma	70,000	25,000	Recurrence	Clinical
			Prediction of drug response	Research

Colon Cancer Recurrence and Response Test

We are in the clinical research phase of developing a test to predict the likelihood of recurrence and response to chemotherapy in patients with early stage colon cancer. Colon cancer is expected to affect approximately 120,000 individuals in the United States in 2005, of which approximately 65,000 early stage patients will need 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.

Prostate Cancer Progression and Recurrence Test

We are in the clinical research phase of developing a test to predict the likelihood of progression and recurrence of prostate cancer in early stage patients. Approximately 250,000 men are expected to be diagnosed with prostate cancer in the United States in 2005, approximately 195,000 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 have established a collaborative agreement with an academic group to conduct initial feasibility studies and to access clinical samples correlated with outcome data in prostate cancer.

Renal Cell Cancer Recurrence and Response Test

We are in the clinical research phase of developing a test to predict the likelihood of recurrence and response to therapy in renal cell cancer. Approximately 40,000 individuals are expected to be diagnosed with renal cell cancer in the United States in 2005. Recently reported studies suggest that some of these patients may respond to new treatments. We have conducted 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 clinical research phase of developing a test to predict the likelihood of response to chemotherapy in early stage, non-small cell lung cancer. Approximately 155,000 individuals are expected to be diagnosed with non-small cell lung cancer in the United States in 2005, of which approximately 25,000 of those patients are 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 research phase of developing a test to predict the likelihood of recurrence and response to therapy for patients with melanoma. Approximately 70,000 individuals are expected to be diagnosed with melanoma in the United States in 2005. 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

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 are marketing our clinical development platform to pharmaceutical companies for exploratory clinical studies.

Epidermal Growth Factor Receptor, or EGFR, Inhibitor Response Test

We are in the clinical research 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 2005, 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.

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.

Research and Development Expenses

Our research and development expenses were $7.1 million, $9.1 million and $10.0 million for the years ended December 31, 2002, 2003 and 2004, respectively, and $4.6 million for the six months ended June 30, 2005.

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. 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 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

55

Table of Contents

use statistical methods to optimize and monitor assay performance and to analyze data from our clinical research and development studies.

Reimbursement

Revenues for clinical laboratory testing services 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, and patients.

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 are reproducible, sensitive, accurate and specific to the patient s tumor. Patients may benefit from treatment decisions based on prediction of recurrence, survival and chemotherapy benefit.

Clinical Utility. Patients are provided a Recurrence Score on a risk continuum that may change decision making regarding the use of adjuvant chemotherapy, which may increase the benefits of treatment while reducing its risks and costs. We believe the large difference in risk of 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. 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 chemotherapy response, 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 August 2005, several regional payors, including Harvard Pilgrim Health Care, Inc. and Highmark Blue Cross Blue Shield, had issued policies supporting reimbursement for our test. In addition, Kaiser Foundation Health Plan, Inc. has entered into a national clinical laboratory services agreement to reimburse us for Onco*type* DX tests performed for their patients. Where policies are not in place, we pursue case-by-case reimbursement. Through this process, as of June 30, 2005, over 180 payors had reimbursed one or more Onco*type* DX tests. We believe that it may take one or more years to achieve successful reimbursement with a majority of payors. However, we cannot predict whether, or under what circumstances, payors will reimburse our products. Payment amounts can also vary across individual policies. Denial of coverage by payors, or reimbursement at inadequate levels, would have a material adverse impact on market acceptance of our products. The current situation with our primary payors is as follows:

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

56

Table of Contents

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 will take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payor denies coverage after final appeal, it may take a substantial amount of time to collect from the patient, and we may not be successful.

In 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.

Medicare and Medicaid. In December 2004, the Northern California Medicare contractor with responsibility for processing and paying claims submitted by us announced that it would not provide coverage for Onco*type* DX for Medicare beneficiaries. It also indicated that there could be some questions concerning whether the hospital must bill Medicare or we can bill Medicare directly. Finally, it questioned which Medicare contractor has jurisdiction to determine coverage for Medicare claims for our test. To date, there is no national coverage determination on Onco*type* DX by Medicare, which means coverage is left to the discretion of the local Medicare contractor. Since the local Medicare contractor responsible for processing claims submitted by us has announced that it would not provide coverage for Onco*type* DX, this has resulted in the denial of Medicare claims. We are appealing these denials through established processes and working with Medicare to establish coverage for our test. During this time, we are not billing Medicare patients directly. However, if we are not successful in establishing coverage through Medicare, we may change this policy and bill future Medicare patients directly, subject to obtaining from patients their advance written consent. We believe that as much as 20% of our future market for Onco*type* DX may be derived from patients covered by Medicare.

Selling and Marketing

Our selling and marketing strategy targets the oncology community, primarily medical and surgical oncologists. Our direct sales approach focuses on the clinical and economic benefits of Onco*type* DX and the scientific validation supporting our product. As of August 31, 2005, our selling and marketing team consisted of 40 employees. Our field staff has significant clinical oncology selling and marketing experience from leading biopharmaceutical, pharmaceutical and specialty reference laboratory companies.

Our marketing strategy focuses on educating physicians, laboratory personnel and other healthcare professionals regarding the development of new genomic technologies and the value of the quantitative information Onco*type* DX provides. We also work closely with national and regional patient advocacy organizations that are focused on breast cancer care. Our customer service representatives are trained to handle inquiries from physicians, patients and other healthcare-providers. We also utilize the Internet for communicating with external constituencies, and our web site contains clinical information for healthcare professionals and educational information for breast cancer patients.

We promote our product through marketing channels commonly used by the biopharmaceutical and pharmaceutical industries, such as sponsored continuing medical education, medical meeting participation and broad-based publication of our scientific and economic data.

Table of Contents

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

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;
- obtain positive reimbursement decisions from payors;
- expand Onco*type* DX for use in other forms of cancer;
- 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. In addition, 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 companies such as Agendia B.V. which offer products or have conducted research to profile gene expression in breast cancer using fresh or frozen tissue. 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, as well as academic and research institutions.

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. Competition among these entities to recruit and retain highly qualified scientific, technical and professional

Table of Contents

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.

Regulation

Medicare and Medicaid Coverage

In determining whether or not Medicare will pay for a service, 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 is the decision of NHIC California, the current local Medicare carrier for California and the contractor with jurisdiction to process claims submitted by us. In December 2004, NHIC published an article on its website stating that it would not provide coverage for Onco*type* DX for Medicare beneficiaries and that there could be some questions concerning which provider must bill Medicare for the test and which contractor had jurisdiction to determine coverage for Medicare claims for our test.

In addition, in February 2005, CMS issued a notice that would affect how the date of service for a laboratory service is determined. Based on this notice, CMS could determine that the date of service for the test is the date on which the patient s initial surgery was performed. As a result, Onco*type* DX could be considered a hospital service, which would mean that we would be required to bill and be paid by the hospital and that the hospital would be required to bill Medicare for the test as part of its prospective payment for the admission or encounter during which the surgery was performed. This could also result in lower reimbursement rates in the event coverage is provided.

We intend to work with Medicare to establish coverage for Medicare beneficiaries, and we are also working with NHIC California and CMS to resolve the issue concerning which entity is required to bill Medicare for our tests. In the meantime, we intend to appeal denials received on a case-by-case basis. We cannot provide any assurance, however, that coverage will be provided in the future by Medicare, that our appeals will ultimately be successful or that other issues will be favorably resolved. 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, no state Medicaid program has decided to pay for the test.

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 code to report Onco*type* DX. Therefore, the test must be reported under a non-specific unlisted procedure code, which is subject to manual review of each claim. Furthermore, because there is no specific code for this test, there is also no set Medicare payment amount.

Table of Contents

We are moving forward with plans to obtain procedure coding, but there is no assurance that a specific procedure code will be adopted or that adequate payment will be assigned if and when a code is adopted.

Several provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 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, which 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.

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 the 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 premarket 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 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 home brew tests. Most home brew tests currently are not subject to premarket review by FDA although analyte-specific reagents or software provided to us by third parties and used by us to perform home brew tests may be subject to review by the FDA prior to marketing. We believe that Onco*type* DX is a type of home brew test. 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 premarket review. At this time, we believe the FDA is reviewing the regulatory status of Onco*type* DX. We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for Onco*type* DX. If premarket review is required, this would adversely affect our business until such review is completed and approval or clearance to market is obtained. If premarket review is required by the 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 the FDA and to the requirements of the FDA and penalties for failure to comply with the requirements of the FDA. Should any of the clinical laboratory device reagents obtained by us from vendors and used in conducting our home brew test be affected by future regulatory actions, we could be adversely affected by those actions, including increased cost of testing or delay, limitation or prohibition on 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 have 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.

Table of Contents

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 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

62

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

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

63

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.

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

New Jersey may require out-of-state laboratories which accept specimens from New Jersey to be licensed in New Jersey. We have spoken with regulators at the New Jersey Department of Health and Senior Services, Clinical Laboratory Improvement Services, and are following their instructions with respect to compliance with New Jersey law. In addition, 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.

Table of Contents

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 patents, 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.

As of August 31, 2005, we had 16 pending U.S. patent applications, including provisional and non-provisional filings. Ten of these U.S. patent applications also have corresponding pending applications under the Patent Cooperation Treaty. We have filed one of our patent applications nationally in Canada, Europe and Japan, three of our patent applications in Canada, Australia, Europe and Japan, and an additional patent application in Canada, Australia and Japan.

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.

From time to time, we may receive, notices of claims of infringement, misappropriation or misuse of other parties proprietary rights. 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

Table of Contents

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

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 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.

Incyte Agreements

In connection with the sale of series C convertible preferred stock to Incyte Corporation in March 2001, we entered into three agreements with Incyte: a LifeSeq collaborative agreement, a patent license agreement and a collaboration and technology transfer agreement. We also entered into a Proteome BioKnowledge Library license agreement with Proteome, Inc., a then wholly owned subsidiary of Incyte.

Under the LifeSeq collaborative agreement, we obtained access to Incyte s genomic database products and received the right to non-exclusively license certain of Incyte s patent rights and know-how relating to the database information. Under the agreement, we paid database access fees to Incyte of $2.0 million in 2002 and $1.0 million in each of 2003 and 2004, or an aggregate of $4.0 million from 2002 to 2004. Upon commercialization of Onco*type* DX, we were required to make a one-time milestone payment of $100,000 and are obligated to pay royalties to Incyte each quarter based on net sales of Onco*type* DX. There are no remaining access fees or milestone payments owing under this agreement. The LifeSeq collaborative agreement continues in perpetuity until terminated. The agreement may be terminated by us or Incyte if the other party materially fails to comply with its obligations under the agreement. If the agreement is terminated, we must pay Incyte an annual fee in order to retain any license we obtained under the agreement. We must continue to pay this fee until the license is terminated or until we make a milestone payment for the license, after which the license will continue in perpetuity.

Under the patent license agreement, we license various classes of patents from Incyte pertaining to the manipulation of genes, the detection of pathological conditions, comparative gene analysis, methods for fabricating tests of biological samples and the use of proteins as markers for cancers. In 2001, we paid Incyte an aggregate of $5.0 million in non-refundable license fees for all classes of patents that we license under this agreement. The non-refundable license fees were one-time payments and no future licensing fees are owing under this agreement. We are also obligated to pay Incyte continuing royalties based on a percentage of our net sales of products which incorporate each class of licensed patents. The patent license agreement continues

until the underlying patent rights expire, unless it is terminated earlier. Incyte may terminate the patent license agreement if we fail to satisfy our obligations under the agreement or otherwise materially breach the agreement. We have the right to terminate the agreement on a patent by patent basis for any reason. If we terminate the agreement early, all of our patent rights under the agreement will expire, but we must continue to pay royalty obligations that we accrued prior to termination. In March 2004, we terminated our rights to some of these patents.

Under the collaboration and technology transfer agreement, we agreed to collaborate on a project with Incyte relating to developing technology for the recovery and extraction of RNA from tissues embedded in paraffin. Under this agreement, Incyte agreed to provide us access to Incyte s technology regarding paraffin extraction for a period of 15 months ending in June 2002. We also agreed to pay Incyte continuing royalties based on the sales of products commercialized using the technology provided by Incyte under this agreement. The collaboration and technology transfer agreement expires on March 30, 2006, but may be terminated earlier if we and Incyte mutually agree in writing. The agreement may also be terminated by us or Incyte if the other party:

materially breaches or defaults under the agreement;

is subject to bankruptcy, insolvency, or dissolution proceedings or makes an assignment for the benefit of creditors; or

if substantially all of the assets of the other party are seized or attached.

All of our rights and obligations under the agreement will terminate when the agreement is terminated, except that termination of the agreement will not release us from any liabilities that accrued prior to termination.

Under the Proteome BioKnowledge Library license agreement, we licensed certain software and were provided access to certain biological databases from Proteome, Inc. This agreement expired in March 2002.

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 and computer and software leases. Under the master security agreement, we granted a security interest to Oxford in all of our goods, equipment, instruments and investment property. The following events would constitute a default by us under the master security agreement:

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;

any of the collateral being subject to attachment or levy;

our dissolving, becoming insolvent, filing for bankruptcy or having a receiver appointed;

a change in our ownership;

a material impairment of Oxford s security interest in the collateral; 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 monthly installments, and principal underlying promissory notes to finance computer and software leases 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 August 31, 2005, the outstanding principal amount under these promissory notes was $3.7 million.

Table of Contents

Employees

As of August 31, 2005, we had 117 full-time employees and two part-time employees, including 19 in research and development, 18 in commercial operations, 14 in medical, three in regulatory, 40 in selling and marketing, 13 in information technology and 12 in administrative functions. None of our employees are covered by collective bargaining arrangements, and our management considers its relationships with our employees to be good.

Properties

We currently sublease approximately 25,000 square feet of laboratory and office space in Redwood City, California under a sublease that expires in February 2006. From June 30, 2005 to the end of its term, the monthly rent under this sublease is $54,000. In September 2005, we entered into a lease directly with the facility owner that has a term of six years. When our existing sublease expires in February 2006, the new lease will apply to the existing 25,000 square feet of laboratory and office space we currently occupy. Under the new lease, we also lease approximately 23,000 square feet of additional space which we expect to first occupy in March 2006. If we first occupy space under this new lease in March 2006, we will be required to make aggregate rent payments of $460,000 in 2006, $730,000 in 2007, $753,000 in 2008, $779,000 in 2009, $799,000 in 2010, $827,000 in 2011 and $139,000 in 2012.

Legal Proceedings

From time to time, we may be party to lawsuits in the ordinary course of business. We are currently not a party to any legal matters.

Table of Contents

MANAGEMENT

Executive Officers and Directors

The following table shows information about our executive officers and directors:

Name	Age	Position(s)
Randal W. Scott, Ph.D.	47	Chairman of the Board and Chief Executive Officer
Kimberly J. Popovits	46	President, Chief Operating Officer and Director
Joffre B. Baker, Ph.D.	57	Chief Scientific Officer
Steven Shak, M.D.	55	Chief Medical Officer
G. Bradley Cole	49	Executive Vice President, Chief Financial Officer and Secretary
Julian C. Baker	39	Director
Brook H. Byers(1)	60	Director
Fred E. Cohen, M.D., Ph.D.(1)(2)	49	Director
Samuel D. Colella(1)(2)(3)	65	Director
Michael D. Goldberg(2)(3)	47	Director
Randall S. Livingston(3)	52	Director

(1) Member of the Compensation Committee.

(2) Member of the Nominating and Corporate Governance Committee.

(3) Member of the Audit Committee.

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

Table of Contents

Discovery Research at Genentech, where he was responsible for Pulmonary Research, Immunology, and Pathology. Prior to joining Genentech, Dr. Shak was an Assistant Professor of Medicine and Pharmacology at the New York University School of Medicine. Dr. Shak holds a B.A. in Chemistry from Amherst College and an M.D. from the New York University School of Medicine, and completed his post-doctoral training at the University of California, San Francisco.

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, and serving as Vice President and General Manager of the Vascular Surgery Business Unit from December 1998 until December 2000 and as Vice President, Finance and IT Systems of the Cardiac and Vascular Surgery Group from December 1997 until November 1998. 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.

Julian C. Baker has served as a director of Genomic Health since January 2001. Mr. Baker is a Managing Member of Baker Bros. Advisors, LLC, which he and his brother, Felix Baker, Ph.D., founded in 2000. Mr. Baker s firm manages Baker Brothers Investments, a family of long-term investment funds for major university endowments and foundations, which are focused on publicly traded life sciences companies. Mr. Baker s career as a fund-manager began in 1994 when he co-founded a biotechnology investing partnership with the Tisch Family, which led to the establishment in 2000 of Baker/ Tisch Advisors, LLC. Mr. Baker is currently a Managing Member of Baker/ Tisch Advisors. Previously, Mr. Baker was employed from 1988 to 1993 by the private equity investment arm of Credit Suisse First Boston Corporation. He is also a director of Incyte Corporation, Neurogen Corporation, Theravance, Inc. and Trimeris, Inc. Mr. Baker holds an A.B. in Social Studies from Harvard University.

Brook H. Byers has served as a director of Genomic Health since January 2001. Mr. Byers is a general partner of Kleiner Perkins Caufield & Byers, a venture capital firm which he joined in 1977. He was the founding president and chairman of four life science companies: Hybritech Inc., IDEC Pharmaceuticals Corporation, InSite Vision Inc. and Ligand Pharmaceuticals Inc. Mr. Byers currently serves as a director of a number of privately held technology, healthcare and biotechnology companies. Mr. Byers holds a B.S. in Electrical Engineering from the Georgia Institute of Technology and an M.B.A. from the Stanford Graduate School of Business.

Fred E. Cohen, M.D., Ph.D., has served as a director of Genomic Health since April 2002. In 2001, Dr. Cohen joined TPG Ventures, a venture capital firm, as a Managing Director. Dr. Cohen is also a Professor of Medicine and Pharmacology at the University of California, San Francisco, where he has taught since July 1988. Dr. Cohen is a director of Matrix Laboratories Limited and a number of privately held companies. Dr. Cohen holds a B.S. in Molecular Biophysics and Biochemistry from Yale University, a Ph.D. in Molecular Biophysics from Oxford University, and an M.D. from Stanford University.

Samuel D. Colella has served as a director of Genomic Health since January 2001. In 1999, Mr. Colella co-founded Versant Ventures, a healthcare and biotechnology venture capital firm. From 1984 to 1999, Mr. Colella was a general partner of Institutional Venture Partners, a venture capital firm. Mr. Colella currently serves as a director of Symyx Technologies, Inc. and a number of privately held technology and biotechnology companies. Mr. Colella has a B.S. in Business and Engineering from the University of Pittsburgh and an M.B.A. from the Stanford Graduate School of Business.

Michael D. Goldberg has served as a director of Genomic Health since October 2001. In January 2005, Mr. Goldberg joined Mohr Davidow Ventures, a venture capital firm, as a general partner. From October 2000 to December 2004, Mr. Goldberg served as the Managing Director of Jasper Capital, a management and financial consultancy business. In 1995, Mr. Goldberg founded OnCare, Inc., an oncology practice management company, and served as Chairman until August 2001 and as Chief Executive Officer until March

70

Table of Contents

1999. Previously, Mr. Goldberg was the founder, President and Chief Executive Officer of Axion Inc., a cancer-focused health care service company. Prior to Axion, Mr. Goldberg was a partner at the venture capital firm Sevin Rosen Funds, and was director of Corporate Development and a member of the Operating Committee at Cetus Corporation. He is also a director of several privately held companies. Mr. Goldberg holds a B.A. in Philosophy from Brandeis University and an M.B.A. from the Stanford Graduate School of Business.

Randall S. Livingston has served as a director of Genomic Health since October 2004. In 2001, Mr. Livingston was appointed Vice President for Business Affairs and Chief Financial Officer of Stanford University. From 1999 to 2001, Mr. Livingston served as Executive Vice President and Chief Financial Officer of OpenTV Corp., a provider of interactive television services. From 1996 until 1999, Mr. Livingston served as a consultant and part-time executive for several Silicon Valley technology companies. Prior to 1996, Mr. Livingston worked for Heartport, Inc., Taligent, Apple Computer, Ingres Corporation and McKinsey & Company. Mr. Livingston holds a B.S. in Mechanical Engineering from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

Board of Directors

Our board of directors currently consists of eight members. Each of Messrs. Baker, Byers, Cohen, Colella, Goldberg and Livingston is an independent director as defined by The Nasdaq Stock Market, Inc. listing standards set forth in Rule 4200(a)(15) adopted by the National Association of Securities Dealers.

Our directors are elected annually to serve until the next annual meeting of stockholders, until their successors are duly elected and qualified or until their earlier death, resignation, disqualification or removal. With limited exceptions, our board of directors is required to have a majority of independent directors at all times. The authorized number of directors may be changed by resolution of the board. Vacancies on the board can be filled by resolution of the board of directors.

Board Committees

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below:

Audit Committee. The audit committee consists of Messrs. Colella, Goldberg and Livingston, with Mr. Livingston serving as the chairman of the committee. The audit committee provides assistance to the board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal accounting controls. The audit committee is responsible for the appointment, compensation, retention and oversight of the independent accountants and takes those actions as it deems necessary to satisfy itself that the accountants are independent of management. Mr. Livingston is our audit committee financial expert as currently defined under the rules of the Securities and Exchange Commission. We believe that our audit committee complies with the requirements of the Sarbanes Oxley Act of 2002, the current rules of The Nasdaq Stock Market and Securities and Exchange Commission rules and regulations.

Compensation Committee. The compensation committee determines our general compensation policies and the compensation provided to our directors and officers. The compensation committee also reviews and determines bonuses for our officers and other employees. In addition, the compensation committee reviews and determines equity-based compensation for our directors, officers, employees and consultants and administers our stock option plans. The current members of the compensation committee are Messrs. Byers, Cohen and Colella, each of whom is a non-management member of our board of directors, with Mr. Colella serving as the chairman of the committee. We believe that our compensation committee complies with the applicable requirements of the Sarbanes-Oxley Act of 2002, the current rules of The Nasdaq Stock Market and Securities and Exchange Commission rules and regulations.

Table of Contents

Nominating and Corporate Governance Committee. The nominating and corporate governance committee is responsible for making recommendations to the board of directors regarding candidates for directorships and the size and composition of the board. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance guidelines and reporting and making recommendations to the board concerning corporate governance matters. The current members of the nominating and governance committee are Messrs. Cohen, Colella and Goldberg, with Mr. Cohen serving as the chairman of the committee. We believe that our nominating and governance committee complies with the applicable requirements of the Sarbanes-Oxley Act of 2002, the current rules of The Nasdaq Stock Market and Securities and Exchange Commission rules and regulations.

Director Compensation

Directors who are employees do not receive any additional compensation for their service on the board. Our non-employee directors are reimbursed for reasonable out-of-pocket expenses incurred in connection with attending board and committee meetings. We currently pay Mr. Goldberg and Mr. Livingston an annual cash retainer of $20,000 each for their services as members of our board of directors. After the closing of this offering, we will pay each non-employee director an annual cash retainer of $20,000 and the chairman of our audit committee of the board of directors an annual cash retainer of $30,000.

During the year ended December 31, 2004 and the three months ended March 31, 2005, we paid Mr. Goldberg $20,000 and $5,000, respectively, for consulting services separate from his services as a member of our board of directors. This consulting agreement was terminated effective as of March 31, 2005.

In October 2001, we granted Mr. Goldberg an option to purchase 25,000 shares of our common stock when he joined our board of directors. The option had an exercise price per share of $0.66 and became fully vested in October 2004. In October 2004, we granted Mr. Livingston an option to purchase 17,340 shares of our common stock when he joined our board of directors. The option has an exercise price per share of $1.33 and vests ratably over a four-year period ending in October 2008. After the closing of this offering, each new non-employee director will receive an initial stock option grant to purchase 16,500 shares of our common stock and each non-employee director will receive an option to purchase 8,250 shares of common stock following each annual meeting of stockholders. See Employee Benefit Plans 2005 Stock Incentive Plan.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee at any time has been one of our officers or employees. There are no familial relationships among any of our directors or officers. No interlocking relationship exists between our board of directors or compensation committee and the board of directors or compensation committee of any other entity, nor has any interlocking relationship existed in the past.

Table of Contents

Executive Compensation

The following table summarizes all compensation paid to our Chief Executive Officer and to our four other most highly compensated executive officers whose total annual salary and bonus exceeded $100,000, for services rendered in all capacities to us during the year ended December 31, 2004.

Summary Compensation Table

		Annual Compensation		Long-Term Compensation		
Name and Position(s)	**Year**	**Salary ($)**	**Bonus ($)**	**Restricted Stock Awards ($)**	**Shares Underlying Options**	**All Other Compensation ($)**
Randal W. Scott, Ph.D. Chief Executive Officer and Chairman	2004	$ 200,000			69,362	
Kimberly J. Popovits President and Chief Operating Officer	2004	275,000			69,361	
Joffre B. Baker, Ph.D. Chief Scientific Officer	2004	275,000			69,362	
Steven Shak, M.D. Chief Medical Officer	2004	275,000			69,362	
G. Bradley Cole(1) Executive Vice President and Chief Financial Officer	2004	120,311			173,407	

(1) Mr. Cole became our Executive Vice President and Chief Financial Officer in July 2004 and his annual salary is $250,000.

Stock option grants to our executive officers have been made in the discretion of our board of directors. Beginning in 2005, stock options grants to our executive officers will be made by the independent members of our board of directors, after considering the recommendations of the compensation committee of the board. The board considered a variety of factors in determining stock option awards, including our business and financial results, the executive s performance, competitive market data for similar positions at comparable companies, and the executive s overall total compensation.

Table of Contents

Stock Options

The following tables set forth certain information for the year ended December 31, 2004 with respect to stock options granted to and exercised by the individuals named in the Summary Compensation Table above. The percentage of total options granted is based on an aggregate of 942,751 shares underlying options granted in 2004.

Option Grants in Last Fiscal Year

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(3)	
Name	**Number of Securities Underlying Options Granted**	**% of Total Options Granted to Employees in Fiscal Year**	**Exercise Price Per Share(1)**	**Expiration Date(2)**	**5%($)**	**10%($)**
Randal W. Scott, Ph.D.	69,362	7.4%	$3.17	12/2/2009	842,308	1,120,501
Kimberly J. Popovits	69,361	7.4	2.88	12/2/2014	1,155,783	1,958,857
Joffre B. Baker, Ph.D.	69,362	7.4	2.88	12/2/2014	1,155,803	1,958,888
Steven Shak, M.D.	69,362	7.4	2.88	12/2/2014	1,155,803	1,958,888
G. Bradley Cole	17,340	1.8	2.88	12/2/2014	288,942	489,708
G. Bradley Cole	156,067	16.6	1.33	6/10/2014	2,843,600	4,650,571

(1) Except for the grant to Dr. Scott, the exercise price for each grant is equal to 100% of the fair market value of our common stock on the date of grant. The exercise price of Dr. Scott s grant is equal to 110% of the fair market value of our common stock on the date of grant.

(2) The options have a term of 10 years, unless issued to a 10% or greater stockholder, in which case they have a term of five years. All options are subject to termination in certain events related to termination of employment. The options vest as to 25% of the shares one year after the date of grant and as to 1/48th of the shares each month thereafter.

(3) Potential realizable values are calculated by:

multiplying the number of shares of our common stock subject to a given option by the initial public offering price of $12.00 per share;

assuming that the aggregate stock value derived from that calculation compounds at the annual 5% or 10% rates shown in the table for the entire five-year or ten-year term of the option, as applicable; and

subtracting from that result the total option exercise price.

The 5% and 10% assumed rates of appreciation are suggested by the rules of the Securities and Exchange Commission and do not represent our estimate or projection of the future common stock price. There can be no assurance that any of the values reflected in the table will be achieved.

Aggregated Option Exercises and Fiscal Year-End Option Value

The following table assumes a fair market value of $12.00 per share, the initial public offering price.

Name	Shares Acquired on Exercise(#)	Value Realized($)	Number of Unexercised Options at Fiscal Year-End(#) Exercisable/Unexercisable	Value of Unexercised In-the-Money Options at Fiscal Year-End($) Exercisable/Unexercisable
Randal W. Scott, Ph.D.			/ 69,362	/ 612,346
Kimberly J. Popovits	100,000	1,234,000	8,670 / 190,747	98,540 / 2,012,202
Joffre B. Baker, Ph.D.			/ 69,362	/ 632,581
Steven Shak, M.D.			/ 69,362	/ 632,581
G. Bradley Cole			/ 173,407	/ 1,823,376

Table of Contents

Employee Benefit Plans

2001 Stock Incentive Plan

General. Our 2001 stock incentive plan was adopted by our board of directors in January 2001 and was subsequently approved by our stockholders.

Administration. The 2001 stock incentive plan provided for the granting of incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, to employees, officers and employee directors and the granting of nonstatutory stock options and stock purchase rights to employees, officers, directors (including non-employee directors) and consultants. The administrator determined the term of options, which was prohibited from exceeding 10 years (five years in the case of an incentive stock option granted to a stockholder holding more than 10% of the voting shares of our company). To the extent an optionee would have the right in any calendar year to exercise for the first time one or more incentive stock options for shares having an aggregate fair market value in excess of $100,000, any such excess options would be treated as nonstatutory stock options.

Authorized Shares. As of August 31, 2005, 459,011 shares of common stock remained available for future issuance under our 2001 stock incentive plan. As of August 31, 2005, options to purchase a total of 1,416,206 shares of common stock were outstanding under the 2001 stock incentive plan at a weighted average exercise price of $1.91 per share. Following the completion of this offering, no shares of our common stock will remain available for future issuance under the 2001 stock incentive plan. Shares that are subject to options that expire, terminate, or are cancelled or as to which options have not been granted under the 2001 stock incentive plan will not be available for option grants or share issuances under our 2005 stock incentive plan after this offering is completed.

Plan Features. Options granted under the 2001 stock incentive plan generally vest at the rate of 1/4 of the total number of shares subject to the options 12 months after the vesting commencement date, and 1/48 of the total number of shares subject to the options each month thereafter. No option may be transferred by the optionee other than by will or the laws of descent or distribution. Each option may be exercised during the lifetime of the optionee only by such optionee. The 2001 stock incentive plan provides that in the event of a recapitalization, stock split or similar capital transaction, we will make appropriate adjustments in order to preserve the benefits of options outstanding under the plan. If we are involved in a merger or consolidation, options granted under the 2001 stock incentive plan may be terminated immediately prior to the effective date of such transaction, unless the surviving or acquiring company assumes them.

2005 Stock Incentive Plan

General. The 2005 stock incentive plan was adopted by our board of directors on September 8, 2005, subject to stockholder approval, and will become effective upon the completion of this offering.

Administration. The 2005 stock incentive plan will be administered by our compensation committee. The 2005 stock incentive plan provides for the grant of options to purchase shares of common stock, restricted stock, stock appreciation rights and stock units. Incentive stock options may be granted only to employees. Nonstatutory stock options and other stock-based awards may be granted to employees, non-employee directors, advisors and consultants. The board of directors will be able to amend or modify the 2005 stock incentive plan at any time, with stockholder approval, if required.

Authorized Shares. 5,000,000 shares of common stock have been authorized for issuance under the 2005 stock incentive plan. Shares subject to awards that expire unexercised or are forfeited or terminated will again become available for issuance under the 2005 stock incentive plan. No participant in the 2005 stock incentive plan can receive option grants, restricted shares, stock appreciation rights or stock units for more than 1,650,000 shares total in any calendar year.

Plan Features. Under the 2005 stock incentive plan:

Nondiscretionary, automatic grants of nonstatutory stock options will be made to outside directors. An outside director joining our board of directors after this offering will be granted automatically an initial option to purchase 16,500 shares upon first becoming a member of our board. The initial option

will vest and become exercisable over four years, with the first 25% of the shares subject to the initial option vesting on the first anniversary of the date of grant date and the remainder vesting monthly thereafter. Immediately after each of our regularly scheduled annual meetings of stockholders, each outside director will be automatically granted a nonstatutory option to purchase 8,250 shares of our common stock, provided the director has served on our board for at least six months. Each annual option will be fully vested and exercisable on the first anniversary of the date of grant or, if earlier, the date of our next annual meeting of stockholders. The options granted to outside directors will have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant, and will become fully vested if we are subject to a change of control.

Generally, if we merge with or into another corporation, we may accelerate the vesting or exercisability of outstanding options and terminate any unexercised options unless they are assumed or substituted for by any surviving entity or a parent or subsidiary of the surviving entity.

The plan terminates ten years after its initial adoption, unless terminated earlier by the board. The board of directors may amend or terminate the plan at any time, subject to stockholder approval where required by applicable law. Any amendment or termination may not impair the rights of holders of outstanding awards without their consent.

401(k) Plan

We have established a tax-qualified employee savings and retirement plan for which our employees are generally eligible. Under our 401(k) plan, employees may elect to reduce their compensation and have the amount of this reduction contributed to the 401(k) plan. We do not make matching contributions. The 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code, so that contributions to the 401(k) plan, and income earned on plan contributions, are not taxable to employees until withdrawn from the plan, and so that contributions by us, if any, will be deductible by us when made.

Indemnification Agreements

We enter into agreements to indemnify our directors and executive officers. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers. Our certificate of incorporation and our bylaws contain provisions that limit the liability of our directors. A description of these provisions is contained under the heading Description of Capital Stock Limitation of Liability and Indemnification Matters.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Table of Contents

RELATED PARTY TRANSACTIONS

Transactions with Officers, Directors and 5% Stockholders

Founder s Stock Purchase Agreements

In October 2000, in connection with our formation, we issued an aggregate of 1,200,000 shares of restricted common stock at a price per share of $0.003 to the following executive officers pursuant to separate founder s stock purchase agreements:

Name	Date of Sale	Number of Shares of Common Stock	Aggregate Purchase Price
Randal W. Scott, Ph.D.	October 16, 2000	600,000	$ 1,800
Joffre B. Baker, Ph.D.	October 16, 2000	300,000	900
Steven Shak, M.D.	October 16, 2000	300,000	900

Under each founder s stock purchase agreement, we were granted a right to repurchase the shares of common stock sold. Our repurchase right lapsed as to 25% of the shares on October 16, 2001, and lapsed with respect to the balance of the shares in 36 equal monthly installments thereafter ending October 16, 2004.

Sales of Preferred Stock

Since January 1, 2002, we sold shares of preferred stock in private financings as follows:

In March 2002, May 2002 and November 2002, we sold 4,073,913 shares of series D preferred stock at a price of $2.30 per share for aggregate consideration of approximately $9.4 million to 11 investors.

In February 2004, March 2004, April 2004 and December 2004, we sold 18,543,980 shares of series E preferred stock at a price of $2.82 per share for aggregate consideration of approximately $52.3 million to 75 investors.

The series D preferred stock and series E preferred stock will convert into one share of common stock for every three shares held upon the closing of this offering. The purchasers of the series D preferred stock and series E preferred stock include the following directors, officers, holders of 5% or more of our securities, and their affiliated entities:

Investor	Number of Shares of Series D Preferred Stock	Number of Shares of Series E Preferred Stock
5% Stockholders:		
Kleiner Perkins Caufield & Byers Affiliated Entities		1,418,440
Versant Ventures Affiliated Entities		1,418,440
TPG Ventures Affiliated Entities	3,043,479	2,464,539
Andrew H., Daniel R., James S. and Thomas J. Tisch		851,064
Julian C. Baker and Felix J. Baker		1,737,589
J.P. Morgan Direct Venture Capital Affiliated Entities		2,739,362
Directors and Executive Officers:		
Joffre B. Baker, Ph.D.		35,460
G. Bradley Cole		35,460

Michael D. Goldberg	35,460
Randall S. Livingston	17,730
Kimberly J. Popovits	35,460
Randal W. Scott, Ph.D.	35,460
Steven Shak, M.D.	35,460

Agreements with Incyte Corporation

In March 2001, we sold 2,252,252 shares of series C preferred stock to Incyte Corporation for aggregate consideration of $5.0 million. Every three shares of series C preferred stock will convert into one share of common stock upon closing of this offering.

The conversion price of the series C preferred stock is subject to adjustment to prevent dilution in the event that we issue additional shares of preferred stock, common stock or common stock equivalents at a purchase price less than the then-effective conversion price. If our board of directors declares any dividends on our capital stock, holders of series C preferred stock and our other outstanding preferred stock will be entitled to receive dividends before holders of our common stock receive any dividends.

In the event of our liquidation, dissolution or winding up, holders of series C preferred stock are entitled, on a basis equal to that of our other outstanding preferred stock, to a liquidation preference prior to payment to holders of common stock of $2.22 per share plus any declared but unpaid dividends. Series C preferred stockholders are entitled to the number of votes they would have upon conversion of their preferred stock into common stock on the record date.

At the time of the series C sale to Incyte, we entered into the following agreements with Incyte and one of its subsidiaries: a LifeSeq collaborative agreement, a patent license agreement, a collaboration and technology transfer agreement and a Proteome BioKnowledge Library license agreement. At that time, Incyte provided genomic information products and services. From January 1, 2002 to December 31, 2004, we paid Incyte an aggregate of $5.4 million under these agreements.

Under the LifeSeq Collaborative Agreement, we license certain of Incyte s patent rights and know-how regarding cloning, DNA sequencing, and data analysis technologies. We use this license to conduct research and develop our clinical diagnostic products. Under the Patent License Agreement, we license various classes of patents from Incyte pertaining to the manipulation of genes, the detection of pathological conditions, comparative gene analysis, methods for fabricating tests of biological samples and the use proteins as markers for cancers. Under the Collaboration and Technology Transfer Agreement, we received access to certain of Incyte s technology regarding paraffin extraction until June 2002. Under the Proteome BioKnowledge Library license agreement, which expired in March 2002, we licensed certain software and were provided access to certain biological databases.

Under the series C preferred stock purchase agreement, Incyte granted us a right, which may be exercised only once, to cause Incyte to purchase an aggregate of $5.0 million of shares of our common stock upon closing this offering at the initial public offering price. We will exercise this right in connection with this offering and sell to Incyte 416,666 shares of common stock at the public offering price per share of $12.00.

As of August 31, 2005, Incyte owned approximately 6.0% of our outstanding capital stock, and will own approximately 6.3% of our outstanding common stock after this offering when we exercise our put right. Randal W. Scott, our Chairman and Chief Executive Officer, was a founder of Incyte and served as a member of its board of directors until December 2001. In addition, Julian C. Baker, one of our directors, is also a member of Incyte s board of directors, and holds shares, directly or beneficially, of both companies.

Registration Rights

We have entered into an investors rights agreement with each of the purchasers of preferred stock listed above. Under this agreement, these and other stockholders will be entitled to registration rights with respect to their shares of common stock issuable upon the automatic conversion of their convertible preferred stock upon the closing this offering. For additional information, see Description of Capital Stock Registration Rights.

Insider Participation in the Offering

Several of our significant existing stockholders, including funds affiliated with Julian C. Baker, Felix J. Baker and Integral Capital Partners VI, L.P. or their affiliates, have indicated an interest in purchasing up to an aggregate of 500,000 shares of our common stock in this offering, less any shares sold to our employees pursuant to our directed share program. However, because indications of interest are not binding upon us or the prospective purchasers, these stockholders may not acquire any shares in this offering.

Indemnification Agreements

We have entered into indemnification agreements with each of our current directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors and executive officers.

Table of Contents

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our common stock as of August 31, 2005, and as adjusted to reflect the shares of common stock to be issued and sold in the offering assuming no exercise of the underwriters over-allotment option, by:

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

Unless otherwise noted below, the address of each person listed on the table is c/o Genomic Health, Inc., 301 Penobscot Drive, Redwood City, California 94063.

We have determined beneficial ownership in accordance with the rules of the Securities Exchange Commission. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to the shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 18,934,044 shares of common stock outstanding on August 31, 2005, which gives effect to the conversion of our preferred stock into an equal number of shares of common stock before the closing of this offering and the dividend we will distribute to our stockholders of record prior to this offering. For the purposes of the table below, we have assumed that 24,367,432 shares of common stock will be outstanding upon completion of this offering, which includes 416,666 shares that we will sell to Incyte Corporation in a concurrent private sale at the initial public offering price of $12.00 per share. The percentage ownership information assumes no exercise of the underwriters over-allotment option and does not reflect the purchase of up to an aggregate of 500,000 shares of our common stock that several of our significant existing stockholders have indicated an interest in purchasing in this offering. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of August 31, 2005. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Table of Contents

Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned	
		Before Offering	After Offering
5% Stockholders:			
Entities Affiliated with Kleiner Perkins Caufield & Byers(1)	2,366,627	12.5%	9.7%
Entities Affiliated with Versant Ventures(2)	2,366,623	12.5	9.7
Entities Affiliated with TPG Ventures(3)	1,910,273	10.1	7.9
Incyte Corporation(4)	1,544,603	6.0	6.3
Andrew H., Daniel R., James S. and Thomas J. Tisch(5)	1,213,760	6.4	5.0
Julian C. Baker and Felix J. Baker(6)	996,299	5.3	4.1
Entities Affiliated with J.P. Morgan Direct Venture Capital(7)	950,056	5.0	3.9
Directors and Named Executive Officers:			
Julian C. Baker(8)	996,299	5.3%	4.1%
Brook H. Byers(9)	2,366,627	12.5	9.7
Fred E. Cohen, M.D., Ph.D.(10)	1,964,895	10.4	8.0
Samuel D. Colella(11)	2,366,623	12.5	9.7
Michael D. Goldberg	48,713	*	*
Randall S. Livingston(12)	10,484	*	*
Joffre B. Baker, Ph.D.(13)	428,478	2.3	1.8
G. Bradley Cole(14)	64,322	*	*
Kimberly J. Popovits(15)	376,456	1.9	1.5
Randal W. Scott, Ph.D.(16)	2,248,796	11.9	9.2
Steven Shak, M.D.	428,478	2.3	1.8
All directors and executive officers as a group (17) (11 persons)	11,300,171	59.3%	46.1%

* Represents beneficial ownership of less than 1%.

(1) Principal address for Kleiner Perkins Caufield & Byers affiliated entities is 2750 Sand Hill Road, Menlo Park, California 94025. Includes 1,556,459 shares held by Kleiner Perkins Caufield & Byers X-A, L.P., 43,899 shares held by Kleiner Perkins Caufield & Byers X-B, L.P., and 766,269 shares held by individual entities affiliated with Kleiner Perkins Caufield & Byers. Mr. Byers, who is also one of our directors, is a managing member of KPCB X Associates, LLC, the general partner of these funds and, as such, has shared voting and investment authority over these shares. However, Mr. Byers disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(2) Principal address for Versant Ventures affiliated entities is 3000 Sand Hill Road, Bldg 4, Suite 210, Menlo Park, California 94025. Includes 2,192,151 shares held by Versant Venture Capital I, L.P., 42,412 shares held by Versant Affiliates Fund I-A, L.P., 89,066 shares held by Versant Affiliates Fund I-B, L.P. and 42,994 shares held by Versant Side Fund I, L.P. Mr. Colella, who is also one of our directors, is a managing director of Versant Ventures I, LLC, the general partner of Versant Venture Capital I, Versant Affiliates Fund I-A, Versant Affiliates Fund I-B and Versant Side Fund. In such capacity, Mr. Colella may be deemed to share voting and investment

power with respect to the shares held by Versant Venture Capital I, Versant Affiliates Fund I-A, Versant Affiliates Fund I-B and Versant Side Fund I. Mr. Colella disclaims beneficial ownership of the shares owned by these funds, except to the extent of his pecuniary interest therein.

(3) Principal address for TPG Ventures affiliated entities is 345 California Street, Suite 2600, San Francisco, California 94104. Includes 573,081 shares owned by TPG Ventures, L.P. and 1,337,192 shares owned by TPG Biotechnology Partners, L.P. Dr. Cohen, who is also one of our directors, is a managing director of Texas Pacific Group Ventures. In such capacity, Dr. Cohen may be deemed to share voting and investment power with respect to the shares held by TPG Ventures, L.P. and TPG Biotechnology Partners, L.P. Dr. Cohen disclaims beneficial ownership of the shares owned by these funds, except to the extent of his pecuniary interest therein.

Table of Contents

(4) Principal address is Experimental Station, Route 141 & Henry Clay Road, Building E336, Wilmington, Delaware 19880. Number of shares of common stock beneficially owned by Incyte is comprised of 1,127,937 shares prior to offering and 416,666 shares purchased by Incyte in a concurrent private sale at the initial public offering price of $12.00 per share.

(5) Principal address is 655 Madison Avenue, 19th Floor, New York, New York 10021. Includes 1,213,760 shares held by Four Partners. By virtue of their status as managing trustees of the trusts which are the general partners of Four Partners, each of Andrew H. Tisch, James S. Tisch, Daniel R. Tisch and Thomas J. Tisch may be deemed to have shared beneficial ownership of shares owned by Four Partners and shared power to vote or direct the vote and dispose or direct the disposition of these shares.

(6) Principal address is 667 Madison Avenue, New York, New York 10021. Includes 173,897 shares owned by Baker Bros. Investments, L.P., 173,897 shares owned by Baker/ Tisch Investments, L.P., 15,314 shares owned by Baker Bros. Investments II, L.P., 158,486 shares owned by Baker Biotech Fund I, L.P., 142,794 shares owned by Baker Biotech Fund II, L.P., 19,583 shares owned by Baker Biotech Fund II (Z), L.P., 116,213 shares owned by Baker Biotech Fund III, L.P., 22,218 shares owned by Baker Biotech Fund III (Z), L.P. and 173,897 shares owned by FBB Associates, a general partnership. Julian C. Baker, who is also one of our directors, and Felix J. Baker, by virtue of their control of entities that have the power to control the investment decisions of Baker Bros. Investments, L.P., Baker/ Tisch Investments, L.P., Baker Bros. Investments II, L.P., Baker Biotech Fund I, L.P., Baker Biotech Fund II, L.P., Baker Biotech Fund II (Z), L.P., Baker Biotech Fund III, L.P., Baker Biotech Fund III (Z), L.P. and FBB Associates, may each be deemed to be the beneficial owner of shares held by such entities and may be deemed to have shared power to vote or direct the vote of and to dispose or direct the disposition of the shares.

(7) Principal address for J.P. Morgan Direct Venture Capital affiliated entities is 522 Fifth Avenue, New York, New York 10036. Includes 735,486 shares held by J.P. Morgan Direct Venture Capital Institutional Investors II LLC, 209,821 shares held by J.P. Morgan Direct Venture Capital Private Investors II LLC and 4,749 shares held by 522 Fifth Avenue Fund, L.P. (collectively, the Global Fund Entities). The investment advisor of the Global Fund Entities is J.P. Morgan Investment Management Inc. (JPMIM). JPMIM has sole voting power with respect to the shares held by the Global Fund Entities. In addition, interests in 522 Fifth Avenue Fund, L.P. are owned both by a wholly owned subsidiary of JPMorgan Chase & Co. (JPM Chase), a publicly traded company, and employees of JPM Chase. As a result, each of JPMIM, JPM Chase and employees of JPM Chase may be deemed beneficial owners of the shares held by the Global Fund Entities, however, each disclaim such beneficial ownership except to the extent of such person s pecuniary interest therein.

(8) Includes 173,897 shares owned by Baker Bros. Investments, L.P., 173,897 shares owned by Baker/ Tisch Investments, L.P., 15,314 shares owned by Baker Bros. Investments II, L.P., 158,486 shares owned by Baker Biotech Fund I, L.P., 142,794 shares owned by Baker Biotech Fund II, L.P., 19,583 shares owned by Baker Biotech Fund II (Z), L.P., 116,213 shares owned by Baker Biotech Fund III, L.P., 22,218 shares owned by Baker Biotech Fund III (Z), L.P. and 173,897 shares owned by FBB Associates, a general partnership. Mr. Baker disclaims beneficial ownership of the shares held by these entities except to the extent of his pecuniary interest therein.

(9) Includes 2,366,627 shares held by Kleiner Perkins Caufield & Byers affiliated entities. Mr. Byers disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(10) Includes 1,910,273 shares held by TPG Ventures affiliated entities, 5,203 shares issuable upon exercise of options that are exercisable within 60 days of July 31, 2005 and 6,068 shares held by family trusts of which Dr. Cohen is a trustee. Dr. Cohen disclaims beneficial ownership of the shares held by the TPG Ventures affiliated entities except to the extent of his pecuniary interest therein.

(11) Includes 2,366,623 shares held by Versant Ventures affiliated entities. Mr. Colella disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(12) Includes 4,335 shares issuable upon exercise of options that are exercisable within 60 days of August 31, 2005.

(13) Includes 116,343 shares held by a family trust of which Dr. Baker is a trustee.

(14) Includes 52,024 shares issuable upon exercise of options that are exercisable within 60 days of August 31, 2005.

(15) Includes 17,342 shares issuable upon exercise of options that are exercisable within 60 days of August 31, 2005.

(16) Includes 5,199 shares held in trust for the benefit of Dr. Scott s minor children, of which Dr. Scott s sister is the trustee.

(17) Includes 78,904 shares issuable upon exercise of options that are exercisable within 60 days of August 31, 2005.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and provisions of our restated certificate of incorporation and bylaws is only a summary. You should also refer to the copies of our restated certificate of incorporation and bylaws that have been filed with the Securities and Exchange Commission as exhibits to our registration statement, of which this prospectus forms a part, and to the provisions of Delaware law.

Upon completion of this offering, after giving effect to the conversion of all outstanding preferred stock into common stock and the amendment of our certificate of incorporation, our authorized capital stock will consist of 100,000,000 shares of common stock, par value $0.0001 per share, and 5,000,000 shares of undesignated preferred stock, par value $0.0001 per share.

Common Stock

As of August 31, 2005, there were 18,197,987 shares of common stock outstanding held by approximately 177 stockholders of record, assuming the automatic conversion of each outstanding share of preferred stock upon the closing of this offering.

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our certificate of incorporation. This means that the holders of a majority of the shares voted can elect all of the directors then standing for election. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of assets legally available at the times and in the amounts that our board of directors may determine from time to time. Upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any outstanding preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock to be issued in this offering, when they are paid for, will be fully paid and nonassessable.

Preferred Stock

Upon the closing of this offering, every three outstanding shares of our series A, B, C and D preferred stock will be converted into one share of common stock. Because the initial public offering price of our common stock is greater than $11.40 per share, upon the closing of this offering every three outstanding shares of series E preferred stock will convert into one share of common stock, or an aggregate of approximately 6,181,326 shares of common stock. If the initial public offering price of our common stock had been less than $11.40 per share, then upon the closing of this offering every three outstanding shares of series E preferred stock would have converted into 1.128 shares of common stock, or an aggregate of approximately 6,972,536 shares of common stock.

On September 8, 2005, our board of directors declared a conditional dividend of 791,210 shares of our common stock, which will be distributed upon the closing of this offering on a pro rata basis to all of our stockholders of record as of the date of this prospectus because the initial public offering price of our common stock is $11.40 or greater. This conditional dividend would not have been distributed if the initial public offering price of our common stock had been lower than $11.40. Our outstanding stock options will be proportionately adjusted as a result of this dividend. Based on our outstanding shares and stock options as of August 31, 2005, we will issue approximately 736,142 shares pursuant to this dividend, less an aggregate of 85 shares for which cash will be paid in lieu of fractional interests, and the number of shares underlying outstanding stock options will be increased by approximately 55,068 shares. The sum of the total number of shares issuable pursuant to the conditional dividend and the additional shares issuable upon exercise of our outstanding stock options as a result of the proportionate adjustments will equal 791,210 shares. The result of the declaration of this conditional dividend is that the sum of the number of outstanding shares of common

Table of Contents

stock and shares underlying outstanding options would have been substantially the same regardless of the price per share of our initial public offering.

Following the conversion, our certificate of incorporation will be amended to delete all references to the prior series of preferred stock, and 5,000,000 shares of undesignated preferred stock will be authorized. Our board of directors will have the authority, without further action by our stockholders, to issue from time to time the preferred stock in one or more series, to establish the number of shares to be included in each series, and to fix the powers, preferences and rights of the shares of each wholly unissued series and any of its qualifications, limitations or restrictions. Our board of directors will also be able to increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by the stockholders.

The board of directors may authorize the issuance of preferred stock with voting or conversion rights that could harm the voting power or other rights of the holders of the common stock, or that could decrease the amount of earnings and assets available for distribution to the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and might harm the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Registration Rights

After this offering, the holders of 17,579,758 shares of common stock issued upon conversion of the preferred stock will be entitled to contractual rights to require us to register those shares under the Securities Act. If we propose to register any of our securities under the Securities Act for our own account, holders of those shares are entitled to include their shares in our registration, provided, among other conditions, that the underwriters of any such offering have the right to limit the number of shares included in the registration. These holders have waived their rights to include their shares in this offering. Six months after the effective date of the registration statement of which this prospectus is a part, and subject to limitations and conditions specified in the investor rights agreement with the holders, holders of a majority of the shares of common stock issued upon conversion of the preferred stock may require us to prepare and file a registration statement under the Securities Act at our expense covering those shares, provided that the shares to be included in the registration have an anticipated aggregate public offering price of at least $10 million. We are not obligated to effect more than two of these stockholder-initiated registrations. Holders of those shares may also require us to file additional registration statements, subject to limitations specified in the investor rights agreement.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

The provisions of Delaware law, our certificate of incorporation and our bylaws described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

Delaware Law

We will be subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, those provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

the transaction is approved by the board before the date the interested stockholder attained that status;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or

Table of Contents

on or after the date the business combination is approved by the board and authorized at a meeting of stockholders by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines business combination to include the following:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

A Delaware corporation may opt out of this provision either with an express provision in its original certificate of incorporation or in an amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out, and do not currently intend to opt out of, this provision. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

Charter and Bylaws

Following the completion of this offering, our certificate of incorporation and bylaws will provide that:

our bylaws may be amended or repealed only by a two-thirds vote of our board of directors or a two-thirds stockholder vote;

no action can be taken by stockholders except at an annual or special meeting of the stockholders called in accordance with our bylaws, and stockholders may not act by written consent;

stockholders may not call special meetings of the stockholders or fill vacancies on the board;

the approval of holders of two-thirds of the shares entitled to vote at an election of directors will be required to amend or repeal the provisions of our certificate of incorporation regarding the inability of stockholders to take action by written consent;

our board of directors will be authorized to issue preferred stock without stockholder approval, as described above; and

we will indemnify officers and directors against losses that they may incur in investigations and legal proceedings resulting from their services to us, which may include services in connection with takeover defense measures.

Limitation of Liability and Indemnification Matters

We have adopted provisions in our certificate of incorporation that limit the liability of our directors for monetary damages for breach of their fiduciary duty as directors, except for liability that cannot be eliminated

Table of Contents

under the Delaware General Corporation Law. Delaware law provides that directors of a company will not be personally liable for monetary damages for breach of their fiduciary duty as directors, except for liabilities:

- for any breach of their duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for unlawful payment of dividend or unlawful stock repurchase or redemption, as provided under Section 174 of the Delaware General Corporation Law; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment or repeal of these provisions requires the approval of the holders of shares representing at least two-thirds of the shares entitled to vote in the election of directors, voting as one class.

Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. Our certificate of incorporation and bylaws also permit us to purchase insurance on behalf of any officer, director, employee or other agent for any liability arising out of that person s actions as our officer, director, employee or agent, regardless of whether Delaware law would permit indemnification. We have entered into separate indemnification agreements with our directors and executive officers that could require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified. We believe that the limitation of liability provision in our certificate of incorporation and the indemnification agreements will facilitate our ability to continue to attract and retain qualified individuals to serve as directors and officers.

Nasdaq Symbol

Our common stock has been approved for quotation on the Nasdaq National Market under the symbol GHDX.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Investor Services.

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. We cannot predict the effect, if any, that market sales of shares or the availability of shares for sale will have on the market price prevailing from time to time. As described below, no shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after the restrictions lapse, or the perception that those sales may occur, could cause the prevailing market price to decrease or to be lower than it might be in the absence of those sales or perceptions.

Sale of Restricted Shares

Upon completion of this offering, we will have outstanding 24,367,432 shares of common stock. The shares of common stock being sold in this offering will be freely tradable, other than by any of our affiliates as defined in Rule 144(a) under the Securities Act or anyone who purchase in our directed share program who are subject to a 180-day lockup agreement, without restriction or registration under the Securities Act. All remaining shares were issued and sold by us in private transactions and are eligible for public sale if registered under the Securities Act or sold in accordance with Rule 144 or Rule 701 under the Securities Act. These remaining shares are restricted securities within the meaning of Rule 144 under the Securities Act.

As a result of the lockup agreements, other contractual restrictions on resale and the provisions of Rules 144, 144(k) and 701 described below, the restricted securities will be available for sale in the public market as follows:

- no shares will be eligible for sale prior to 180 days after the date of this prospectus;
- 19,350,710 shares will be eligible for sale upon the expiration of the lock-up agreements, described below, beginning 180 days after the date of this prospectus (subject to extension) and when permitted under Rule 144, 144(k) or 701; and
- 641,691 shares will be eligible for sale upon the exercise of vested options 180 days after the date of this prospectus.

Lock-up Agreements

Our directors, executive officers and substantially all of our stockholders and optionholders, who collectively hold an aggregate of approximately 18,349,249 shares of common stock (representing approximately 97% of our shares of common stock outstanding prior to this offering), have agreed that they will not sell any common stock owned by them without the prior written consent of J.P. Morgan Securities Inc. and Lehman Brothers Inc. on behalf of the underwriters for a period of 180 days from the date of this prospectus, subject to extension as described below. At any time and without public notice, J.P. Morgan Securities Inc. and Lehman Brothers Inc. may in their sole discretion release some or all of the securities from these lock-up agreements. To the extent shares are released before the expiration of the lockup period and these shares are sold into the market, the market price of our common stock could decline. Immediately following the 180-day lockup period, shares of our common stock outstanding after this offering will become available for sale, subject to legal restrictions on resale. The 180-day lock-up period may be extended under certain circumstances where we release, or pre-announce a release of, our earnings or announce material news or a material event shortly before or after the termination of the 180-day period. See Underwriting Lock-Up Agreements.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus, a person deemed to be our affiliate, or a person holding restricted shares who beneficially owns shares that were

Table of Contents

not acquired from us or our affiliate within the previous one year, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the then outstanding shares of common stock, or approximately 243,674 shares immediately after this offering, assuming no exercise of the underwriters over-allotment option; or
- the average weekly trading volume of the common stock during the four calendar weeks preceding the date on which notice of the sale is filed with the Securities and Exchange Commission.

Sales under Rule 144 are subject to requirements relating to manner of sale, notice and availability of current public information about us.

Rule 144(k)

A person, or persons whose shares are aggregated, who is not deemed to have been our affiliate at any time during the 90 days immediately preceding the sale, and who beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner who was not an affiliate of ours, may sell restricted securities after this offering under Rule 144(k) without complying with the volume limitations, manner of sale provisions, public information or notice requirements of Rule 144. We currently expect that approximately 1,977,962 shares will qualify as Rule 144(k) shares within 180 days after the date of this prospectus; however, this number may increase or decrease depending on a particular stockholder s status as an affiliate during the 90 days immediately preceding the sale.

Rule 701

Subject to various limitations on the aggregate offering price of a transaction and other conditions, Rule 701 may be relied upon with respect to the resale of securities originally purchased from us by our employees, directors, officers, consultants or advisers prior to the closing of this offering, pursuant to written compensatory benefit plans or written contracts relating to the compensation of such persons. In addition, the Securities and Exchange Commission has indicated that Rule 701 will apply to stock options granted by us before this offering, along with the shares acquired upon exercise of those options. Securities issued in reliance on Rule 701 are deemed to be restricted securities and, beginning 90 days after the date of this prospectus, unless subject to the contractual restrictions described above, may be sold by persons other than affiliates subject only to the manner of sale provisions of Rule 144 and by affiliates under Rule 144 without compliance with the minimum holding period requirements.

Stock Options

We intend to file a registration statement under the Securities Act covering 5,000,000 shares of common stock reserved for issuance under our stock plans. This registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing. Accordingly, shares registered under this registration statement will be available for sale in the open market, unless those shares are subject to vesting restrictions with us or the contractual restrictions described above.

Registration Rights

In addition, after this offering, the holders of approximately 17,579,758 shares of common stock will be entitled to rights to cause us to register the sale of those shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares, other than shares purchased by our affiliates, becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See Description of Capital Stock Registration Rights.

Table of Contents

UNDERWRITING

J.P. Morgan Securities Inc. and Lehman Brothers Inc. are the joint book-running managers and, together with Piper Jaffray & Co., Thomas Weisel Partners LLC and JMP Securities LLC, are acting as representatives of the underwriters. Under the terms of an Underwriting Agreement, which is filed as an exhibit to the registration statement, each of the underwriters named below has severally agreed to purchase from us the respective number of common stock shown opposite its name below:

Underwriter	Number of Shares
J.P. Morgan Securities Inc.	1,672,073
Lehman Brothers Inc.	1,672,073
Piper Jaffray & Co.	718,896
Thomas Weisel Partners LLC	718,896
JMP Securities LLC	234,784
Total	5,016,722

The underwriting agreement provides that the underwriters obligation to purchase shares of common stock depends on the satisfaction of the conditions contained in the underwriting agreement including:

the obligation to purchase all of the shares of common stock offered hereby, if any of the shares are purchased;

the representations and warranties made by us to the underwriters are true in all material respects;

there is no material change in the financial markets; and

we deliver customary closing documents to the underwriters.

Commissions and Expenses

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares. The underwriting fee is the difference between the initial price to the public and the amount the underwriters pay to us for the shares.

	No Exercise	Full Exercise
Per share	$ 0.882	$ 0.882
Total	$ 4,424,749	$ 5,088,461

The representatives of the underwriters have advised us that the underwriters propose to offer the shares of common stock directly to the public at the public offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of $0.53 per share. The underwriters may allow, and the selected dealers may re-allow, a discount from the concession not in excess of $0.10 per share to other dealers. After the offering, the representatives may change the offering price and other selling terms.

The expenses of the offering that are payable by us are estimated to be $1.8 million (exclusive of underwriting discounts and commissions).

Option to Purchase Additional Shares

We have granted the underwriters an option exercisable for 30 days after the date of the underwriting agreement, to purchase, from time to time, in whole or in part, up to an aggregate of 752,508 shares at the public offering price less underwriting discounts and commissions. This option may be exercised if the underwriters sell more than 5,016,722 shares in connection with this offering. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter s percentage underwriting commitment in the offering as indicated in the table at the beginning of this Underwriting section.

Table of Contents

Lock-up Agreements

We, all of our directors and executive officers and substantially all of our stockholders and optionholders have agreed that, without the prior written consent of each of J.P. Morgan Securities Inc. and Lehman Brothers Inc. on behalf of the underwriters, we and they will not, subject to some exceptions, and limited extensions in certain circumstances, directly or indirectly, offer, pledge, announce the intention to sell, sell, contract to sell, sell an option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of (or enter into any transaction or device, that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any common stock or any securities which may be converted into or exchanged for any common stock or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock for a period of 180 days from the date of this prospectus.

The 180-day restricted period described in the preceding paragraph will be extended if:

during the last 17 days of the 180-day restricted period we issue an earnings release or announce material news or a material event relating to us; or

prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or material event.

Offering Price Determination

Prior to this offering, there has been no public market for our common stock. The initial public offering price has been negotiated between the representatives and us. In determining the initial public offering price of our common stock, the representatives considered:

the history and prospectus for the industry in which we compete,

our financial information,

the ability of our management and our business potential and earning prospects,

the prevailing securities markets at the time of this offering, and

the recent market prices of, and the demand for, publicly traded shares of generally comparable companies.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and to contribute to payments that the underwriters may be required to make for these liabilities.

Stabilization, Short Positions and Penalty Bids

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Securities Exchange Act of 1934:

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is

not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional

Table of Contents

shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the Nasdaq National Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representatives on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter s or selling group member s web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

The Nasdaq National Market

Our shares of common stock have been approved for quotation on the Nasdaq National Market under the symbol GHDX.

Discretionary Sales

The underwriters have informed us that they do not intend to confirm sales to discretionary accounts that exceed 5% of the total number of shares offered by them.

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Relationships

The underwriters and their affiliates may in the future perform investment banking and advisory services for us from time to time for which they may in the future receive customary fees and expenses. The

Table of Contents

underwriters and their affiliates may, from time to time, engage in transactions with or perform services for our affiliates and us in the ordinary course of their business. Certain affiliates of J.P. Morgan Securities Inc., one of the representatives of the underwriters, purchased an aggregate of 869,565 shares of our series D preferred stock for approximately $2.0 million in May 2002.

Directed Share Program

At our request, the underwriters have reserved at the initial public offering price up to 10% of the shares offered hereby for our employees, less any shares sold to several of our significant existing stockholders as described below. The number of shares available for sale to the general public will be reduced to the extent our employees purchase reserved shares. Any reserved shares not purchased will be offered by the underwriters to the general public on the same basis as the other shares offered hereby. The directed share program will be arranged through one of our underwriters, Lehman Brothers.

Insider Participation in the Offering

Several of our significant existing stockholders, including funds affiliated with Julian C. Baker, Felix J. Baker and Integral Capital Partners VI, L.P. or their affiliates, have indicated an interest in purchasing up to an aggregate of 500,000 shares of our common stock in this offering, less any shares sold to our employees pursuant to our directed share program. However, because indications of interest are not binding upon us or the prospective purchasers, these stockholders may not acquire any shares in this offering.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of shares of common stock being offered hereby to the public in that Relevant Member State prior to the publication of a prospectus in relation to such shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive. However, with effect from and including the Relevant Implementation Date, it may make an offer of shares of our common stock to the public in that Relevant Member State at any time:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts; or

in any other circumstances which do not require the publication by the issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer of shares of our common stock to the public in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe such shares, as may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/ EC and includes any relevant implementing measure in each Relevant Member State.

Germany

The shares have not been and will not be offered to the public within the meaning of the German Sales Prospectus Act (*Verkaufsprospektgesetz*) or the German Investment Act (*Investmentgesetz*). The shares have not been and will not be listed on a German exchange. No sales prospectus pursuant to the German Sales Prospectus Act has been or will be published or circulated in Germany or filed with the German Federal Financial Supervisory Authority (*Bundesanstalt für Finanzdienstleistungsaufsicht*) or any other governmental or regulatory authority in Germany. This prospectus

does not constitute an offer to the public in Germany and it does not serve for public distribution of the shares in Germany. Neither this prospectus, nor any other

document issued in connection with this offering, may be issued or distributed to any person in Germany except under circumstances which do not constitute an offer to the public within the meaning of the German Sales Prospectus Act or the German Investment Act.

Italy

The offering has not been registered with the Commissione Nazionale per le Società e la Borsa (CONSOB) pursuant to Italian securities legislation. The shares may not be offered or sold nor may the prospectus or any other offering materials be distributed in the Republic of Italy unless such offer, sale or distribution is:

(1) made by an investment firm, bank or financial intermediary permitted to conduct such activities in the Republic of Italy in accordance with Legislative Decree No. 385 of September 1, 1993 (Decree No. 385), Legislative Decree No. 58 of February 24, 1998, CONSOB Regulation No. 11971 or May 14, 1999 and any other applicable laws and regulations;

(2) made (i) to professional investors (operatori qualificati) as defined in Article 31, second paragraph of CONSOB Regulation No. 11422 of July 1, 1998, as amended, or Regulation No. 11522, (ii) in circumstances where an exemption from the rules governing solicitations to the public at large applies pursuant to Article 100 of Legislative Decree No. 58 of February 24, 1998 and Article 33, first paragraph, of CONSOB Regulation No. 11971 of May 14, 1999, as amended or (iii) to persons located in the Republic of Italy who submit an unsolicited request to purchase shares; and

(3) in compliance with all relevant Italian securities and tax laws and regulations.

Switzerland

The shares may not be offered or sold to any investors in Switzerland other than on a non-public basis. This prospectus does not constitute a prospectus within the meaning of Article 652a and Art. 1156 of the Swiss Code of Obligations (*Schweizerisches Obligationenrecht*). Neither this offering nor the shares have been or will be approved by any Swiss regulatory authority.

United Kingdom

Each underwriter has represented, warranted and agreed that:

(1) it has not offered or sold and, prior to the expiry of a period of six months from the closing date, will not offer or sell any shares to persons in the United Kingdom except to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or agent) for the purposes of their businesses or otherwise in circumstances which have not resulted and will not result in an offer to the public in the United Kingdom within the meaning of the Public Offers of Securities Regulations 1995;

(2) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000, or FSMA) received by it in connection with the issue or sale of any shares in circumstances in which section 21(1) of the FSMA does not apply to the Issuer; and

(3) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Table of Contents

LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Pillsbury Winthrop Shaw Pittman LLP, San Francisco and Palo Alto, California. An entity in which attorneys and former attorneys of Pillsbury Winthrop Shaw Pittman LLP are members, and certain attorneys of Pillsbury Winthrop Shaw Pittman LLP, own beneficially an aggregate of 19,035 shares of our common stock. Selected legal matters relating to the offering will be passed upon for the underwriters by Simpson Thacher & Bartlett LLP, Palo Alto, California.

EXPERTS

The consolidated financial statements of Genomic Health, Inc. at December 31, 2003 and 2004, and for each of the three years in the period ended December 31, 2004, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement under the Securities Act of 1933 with respect to the common stock offered by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement, exhibits and schedules for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract or other document are only summaries. With respect to any contract or document filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract or document, and each statement in this prospectus regarding that contract or document is qualified by reference to the exhibit. A copy of the registration statement and its exhibits and schedules may be inspected without charge at the Securities and Exchange Commission s public reference room, located at 100 F Street, N.E., Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference room. Our Securities and Exchange Commission filings are also available to the public from the Securities and Exchange Commission s website at www.sec.gov.

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934 and we intend to file reports, proxy statements and other information with the Securities and Exchange Commission.

GENOMIC HEALTH, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

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, 2003 and 2004 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, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genomic Health, Inc. at December 31, 2003 and 2004 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Palo Alto, California
May 13, 2005,
except for the ninth paragraph of Note 1,
as to which the date is September 23, 2005.

Table of Contents

Genomic Health, Inc.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31,		June 30,	Pro Forma Stockholders Equity at June 30, 2005
	2003	2004	2005	
			(Unaudited)	(Unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 11,062	$ 38,275	$ 25,231	
Accounts receivable			100	
Prepaid expenses and other current assets	563	901	2,265	
Employee note receivable - current portion		75	75	
Total current assets	11,625	39,251	27,671	
Employee note receivable - long-term portion		38		
Property and equipment, net	1,288	2,116	3,010	
Restricted cash	50			
Other assets	133	133	151	
Total assets	$ 13,096	$ 41,538	$ 30,832	
Liabilities and stockholders equity (deficit)				
Current liabilities:				
Accounts payable	$ 827	$ 1,101	$ 2,009	
Accrued compensation	342	603	747	
Accrued expenses and other current liabilities	249	776	832	
Notes payable - current portion			777	
Note payable due to related party	161			
Total current liabilities	1,579	2,480	4,365	
Notes payable - long-term portion			2,483	
Convertible preferred stock, $0.0001 par value; 101,216,958 shares authorized, 29,936,839, 48,480,819 and 48,480,819 shares issued and outstanding at December 31, 2003 and 2004 and June 30, 2005 (unaudited), respectively; aggregate liquidation preference of $103,599 at December 31, 2004 and June 30, 2005 (unaudited); no shares issued and outstanding pro forma	51,064	103,212	103,212	$
Stockholders equity (deficit):				

Common stock, $0.0001 par value; 105,000,000 shares authorized, 1,674,113, 1,875,530 and 1,932,921 shares issued and outstanding at December 31, 2003 and 2004 and June 30, 2005 (unaudited), respectively; 18,884,404 shares issued and outstanding pro forma (unaudited)	1	1	1	2
Additional paid-in capital	279	4,123	5,085	108,296
Deferred stock-based compensation		(3,456)	(3,793)	(3,793)
Accumulated deficit	(39,827)	(64,822)	(80,521)	(80,521)
Total stockholders equity (deficit)	(39,547)	(64,154)	(79,228)	$ 23,984
Total liabilities and stockholders equity (deficit)	$ 13,096	$ 41,538	$ 30,832	

See accompanying notes.

Table of Contents

Genomic Health, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	Year Ended December 31,			Six Months Ended June 30,	
	2002	2003	2004	2004	2005
				(unaudited)	
Revenues:					
Product revenues	$	$	$ 227	$ 33	$ 1,585
Contract revenues		125	100		100
Total revenues		125	327	33	1,685
Operating expenses:					
Cost of product revenues			1,828	931	2,874
Research and development	7,053	9,069	10,040	5,182	4,630
Selling and marketing	754	2,805	9,856	4,449	7,415
General and administrative	3,753	3,686	3,869	1,832	2,787
Total operating expenses	11,560	15,560	25,593	12,394	17,706
Loss from operations	(11,560)	(15,435)	(25,266)	(12,361)	(16,021)
Interest income	502	199	295	121	393
Interest expense	(13)	(14)	(4)	(3)	(72)
Other (expense) income, net	3		(20)	(20)	1
Net loss	$ (11,068)	$ (15,250)	$ (24,995)	$ (12,263)	$ (15,699)
Basic and diluted net loss per share	$ (11.95)	$ (12.43)	$ (14.38)	$ (7.26)	$ (8.28)
Shares used in computing basic and diluted net loss per share	925,814	1,226,444	1,737,652	1,687,964	1,895,625
Pro forma net loss per share (unaudited)			$ (1.60)		$ (0.83)
Shares used in computing pro forma net loss per share (unaudited)			15,632,759		18,847,108

See accompanying notes.

Table of Contents

Genomic Health, Inc.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)
(In thousands, except share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-based Compensation	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2001	25,862,926	$ 41,783	1,373,750	$	$ 27		$ (13,509)	$ (13,482)
Issuance of Series D convertible preferred stock in March, May and November 2002 to investors at $2.30 per share for cash (net of issuance costs of $79)	4,073,913	9,290						
Issuance of common stock to consultants upon exercise of stock options at $0.66 to $0.69 per share for cash			13,133	1	9			10
Issuance of common stock to an employee upon exercise of stock options at $0.66 per share for cash			3,333		2			2
Stock-based compensation related to consultant options					36			36
Net loss and comprehensive loss							(11,068)	(11,068)
Balance at December 31, 2002	29,936,839	51,073	1,390,216	1	74		(24,577)	(24,502)
Issuance of common stock to consultants upon exercise of stock options at $0.60 to $0.69 per share for cash			36,500		25			25

Issuance of common stock to employees upon exercise of stock options at $0.60 to $0.69 per share for cash			247,396		163		163
Series E issuance costs		(9)					
Stock-based compensation related to consultant options					17		17
Net loss and comprehensive loss						(15,250)	(15,250)
Balance at December 31, 2003	29,936,839	51,064	1,674,113	1	279	(39,827)	(39,547)
Issuance of common stock to consultants upon exercise of stock options at $0.66 to $1.38 per share for cash			1,125		1		1
Repurchase of common stock issued to founders			(13,672)				
Issuance of common stock to employees upon exercise of stock options at $0.66 to $1.38 per share for cash			213,964		143		143
Issuance of Series E convertible preferred stock at $2.82 per share for cash (net of issuance costs of $146)	18,543,980	52,148					
Deferred stock-based compensation					3,647	(3,647)	
Amortization of deferred stock-based compensation						191	191
Stock-based compensation related to consultant options					53		53
Net loss and comprehensive loss						(24,995)	(24,995)

Balance at December 31, 2004	48,480,819	103,212	1,875,530	1	4,123	(3,456)	(64,822)	(64,154)
Issuance of common stock to employees upon exercise of stock options at $0.66 to $1.38 per share for cash (unaudited)			56,058		56			56
Issuance of common stock to consultants upon exercise of stock options at $0.69 to $3.00 per share for cash (unaudited)			1,333		2			2
Stock-based compensation related to consultant options (unaudited)					58			58
Deferred stock-based compensation (unaudited)					846	(846)		
Amortization of deferred stock-based compensation (unaudited)						509		509
Net loss and comprehensive loss (unaudited)							(15,699)	(15,699)
Balance at June 30, 2005 (unaudited)	48,480,819	$ 103,212	1,932,921	$ 1	$ 5,085	$ (3,793)	$ (80,521)	$ (79,228)

See accompanying notes.

Table of Contents

Genomic Health, Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,			Six Months Ended June 30,	
	2002	2003	2004	2004	2005
				(Unaudited)	
Operating activities					
Net loss	$ (11,068)	$ (15,250)	$ (24,995)	$ (12,263)	$ (15,699)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization	642	824	1,008	486	690
Amortization of deferred stock-based compensation			191	9	509
Non-employee stock-based compensation expense	36	17	53	10	58
Loss on disposal of property and equipment	6		20	20	(31)
Changes in assets and liabilities:					
Accounts receivable					(100)
Employee note receivable	18		(113)		38
Prepaid expenses and other current assets	(366)	(61)	(338)	(243)	(1,364)
Other assets	3				(18)
Accounts payable	(105)	655	274	332	908
Note payable to related party	(1,527)				
Accrued expenses and other liabilities	17	116	527	148	144
Accrued compensation		155	261	85	56
Net cash used in operating activities	(12,344)	(13,544)	(23,112)	(11,416)	(14,809)
Investing activities					
Purchase of property and equipment	(737)	(739)	(1,856)	(797)	(1,553)
Restricted cash	106		50		
Net cash used in investing activities	(631)	(739)	(1,806)	(797)	(1,553)
Financing activities					
Proceeds from (repayment of) long-term debt due to related party	313	(152)	(161)	(79)	
Proceeds from notes payable					3,260
Proceeds from issuance of common stock	11	188	144	32	58
Sale of property and equipment					
	9,291	(9)	52,148	29,919	

Net proceeds from issuance of convertible preferred stock					
Net cash provided by financing activities	9,615	27	52,131	29,872	3,318
Net increase (decrease) in cash and cash equivalents	(3,360)	(14,256)	27,213	17,659	(13,044)
Cash and cash equivalents at the beginning of period	28,678	25,318	11,062	11,062	38,275
Cash and cash equivalents at the end of period	$ 25,318	$ 11,062	$ 38,275	$ 28,721	$ 25,231
Supplemental disclosure of cash flow information					
Cash paid for interest	$ 1	$ 26	$ 4	$ 3	$ 72

See accompanying notes.

Table of Contents

Genomic Health, Inc.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Information subsequent to December 31, 2004 and pertaining to June 30, 2005 and the six months ended June 30, 2004 and 2005 is unaudited)

Note 1. The Company and Summary of Significant Accounting Policies

Description of Business and Principles of Consolidation

Genomic Health, Inc. (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.

Since the Company s inception in 2000, the focus of its operations has consisted principally of the development of initial products, raising capital, establishing facilities and recruiting personnel. In January 2004, the Company commercialized its first product, Onco*type* DX, a genomic test used to quantify the likelihood of recurrence in early stage breast cancer.

The Company has incurred significant losses and expects to incur additional losses in the foreseeable future as commercial and development efforts continue. If financing arrangements contemplated by management are not realized, the Company may have to seek other sources of capital or re-evaluate its operating plan.

In October 2003, the Company established a wholly owned subsidiary, Oncotype Laboratories, Inc. The entity is currently inactive. All intercompany transactions are eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ, and those differences may be material.

Unaudited Interim Consolidated Results

The accompanying consolidated balance sheet as of June 30, 2005, the consolidated statements of operations and cash flows for the six months ended June 30, 2004 and 2005 and the consolidated statements of convertible preferred stock and stockholders equity (deficit) for the six months ended June 30, 2005 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all the adjustments, which include only normal recurring adjustments, necessary to present fairly the Company s financial position as of June 30, 2005. Results for the six months ended June 30, 2004 and 2005 are not necessarily indicative of the results to be expected for the year ended December 31, 2005 or for any future interim period or for any future year.

Unaudited Pro Forma Information

The pro forma information assumes all of the convertible preferred stock outstanding will automatically convert into 16,160,273 shares of common stock, based on the shares of convertible preferred stock outstanding at June 30, 2005. The Company has filed a registration statement with the Securities and Exchange Commission to sell shares of its common stock to the public. If the initial public offering price of the Company s common stock is less than $11.40 per share, every three shares of Series A, B, C, and D preferred stock will convert into one share of common stock and every three shares of Series E preferred stock will convert into 1.128 shares of common stock, or an aggregate of 16,951,483 shares of common stock. Unaudited pro forma stockholders equity, as adjusted for the assumed conversion of the convertible preferred stock, is set forth on the consolidated balance sheet.

Table of Contents

On September 8, 2005, the board of directors of the Company declared a conditional stock dividend of 791,210 shares to stockholders of record prior to the date of the Company s initial public offering. The conditional stock dividend will be distributable if the initial public offering price of the Company s common stock is greater than or equal to $11.40 a share. The conditional stock dividend, if paid, will be a ratable distribution to all holders of the Company s common stock outstanding prior to closing of the initial public offering and after giving effect to the conversion of all of the Company s outstanding preferred stock. The Company s outstanding stock options will be proportionately adjusted in the event the conditional stock dividend is distributed. If the conditional stock dividend is distributed, it will be recorded in the quarter ended September 30, 2005. This dividend has no material impact on the pro forma balance sheet because of the Company s accumulated deficit. The 791,210 shares have been included in the pro forma net loss per share calculation.

Stock Split

On September 8, 2005, the board of directors of the Company approved a 1-for-3 reverse stock split of the Company s outstanding shares of common stock. The reverse stock split was effected on September 23, 2005. All common share and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect this stock split.

Cash and Cash Equivalents

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 amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in the fair value of available-for-sale securities below their cost that are deemed to be other-than-temporary are reflected in other income. The cost of securities sold is based on the specific identification method. Interest on investments is included in interest income.

In connection with a bank agreement pertaining to a corporate credit card account, the Company was required to hold a certificate of deposit at 100% of the credit limit per account, which totaled $50,000 as of December 31, 2003, and was classified as restricted cash. During July 2004, this restriction was removed by the bank and the amount was removed from 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, 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.

Long-lived Assets

The Company reviews long-lived assets, including property and equipment, 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

Table of Contents

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 June 30, 2005, 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 contracts with biopharmaceutical and pharmaceutical companies. Research and development costs are expensed as incurred.

Concentration of Risk

One customer accounted for approximately 9% of the Company s total revenue for the six months ended June 30, 2005, and approximately 11% of the Company s total revenue for the quarter ended June 30, 2005.

Comprehensive Loss

The Company displays comprehensive loss and its components as part of the statements of convertible preferred stock and stockholders equity (deficit). Comprehensive loss consists entirely of net loss.

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, 2004 or June 30, 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

As permitted by Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), as amended by SFAS No. 148, the Company has elected to follow Accounting Principles Board (APB) Opinion 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations in accounting for stock option grants to employees using the intrinsic value method and to disclose the pro forma effect of SFAS 123. The information regarding net loss and net loss per share prepared in accordance with SFAS 123 has been determined as if the Company had accounted for employee

Table of Contents

stock options under the fair value method prescribed by SFAS 123 and the net loss per share method under SFAS 148. The resulting effect on net loss and net loss per share pursuant to SFAS 123 is not likely to be representative of the effects in future years, due to subsequent years including additional grants and years of vesting.

The Company estimated the fair value of these options at the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	December 31,			June 30,	
	2002	2003	2004	2004	2005
				(Unaudited)	
Volatility factor	80%	80%	80%	80%	80%
Average risk-free interest rate	4.0%	2.0%	2.8%	2.0%	4.0%
Dividend yield	0%	0%	0%	0%	0%
Expected life of options	4 years	4 years	4 years	4 years	4 years

In connection with the grant of certain stock options to employees during the year ended December 31, 2004 and six months ended June 30, 2005, the Company recorded deferred stock compensation within stockholders equity (deficit) of $3,647,000 and $846,000, respectively. This represents the difference between the reassessed fair value of common stock and the option exercise price at the date of grant. Such amounts will be amortized over the vesting period of the applicable options on a straight-line basis. For the year ended December 31, 2004 and six months ended June 30, 2005, the Company recorded stock-based compensation expense of $191,000 and $509,000, respectively. The expected future amortization expense under APB 25 for deferred stock-based compensation for stock options granted through June 2005, is as follows (in thousands):

Years Ending December 31,	
2005 (remainder of the year)	$ 559
2006	1,117
2007	1,117
2008 (and thereafter)	1,000
	$ 3,793

For purposes of disclosures pursuant to SFAS 123, as amended by SFAS 148, the estimated fair value of options is amortized to expense straight-line over the options vesting period. The following table shows the pro forma effect on net loss and net loss per common share if the fair value provisions of SFAS 123 had been applied (in thousands):

	December 31,			June 30,	
	2002	2003	2004	2004	2005
				(Unaudited)	
Net loss as reported	$ (11,068)	$ (15,250)	$ (24,995)	$ (12,263)	$ (15,699)
Add: Total stock-based employee compensation expense included in net loss			191	9	509
	(27)	(87)	(320)	(63)	(633)

Deduct: Total stock-based employee compensation expense determined under the fair-value based method for all awards					
Pro forma net loss	$ (11,095)	$ (15,337)	$ (25,124)	$ (12,317)	$ (15,823)
Loss per share applicable to common stockholders:					
Basic and diluted, as reported	$ (11.95)	$ (12.43)	$ (14.38)	$ (7.26)	$ (8.28)
Basic and diluted, pro forma	$ (11.98)	$ (12.51)	$ (14.46)	$ (7.30)	$ (8.35)

Table of Contents

Equity instruments granted to nonemployees are valued using the Black-Scholes method and accounted for as prescribed by SFAS 123 and Emerging Issues Task Force 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 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 and 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 the criteria set forth in (1) and (2) above are met, and (3) and (4) 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 recognized at the time cash is collected.

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.

Recently Issued Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payment,* which is a revision of SFAS 123, *Accounting for Stock-Based Compensation.* SFAS 123(R) is effective for public companies for the first interim or annual period beginning after June 15, 2005, supersedes APB 25, and amends SFAS No. 95, *Statement of Cash Flows.* Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123, however, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The new standard will be effective for the Company beginning January 1, 2006.

Under SFAS 123(R), the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive adoption option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options at the beginning of the first quarter of adoption of SFAS 123(R), while the retroactive method would record compensation expense for all unvested stock options beginning with the first period restated.

Table of Contents

The Company is evaluating the requirements of SFAS 123(R) and expects that its adoption may have a material impact on the Company s consolidated results of operations and earnings per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123(R), and has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123.

Loss Per Share

Basic loss per share is calculated by dividing the loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period less the weighted average unvested common shares subject to repurchase and without consideration for potential common shares. Diluted loss per share is computed by dividing the loss applicable to common stockholders 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.

The unaudited pro forma basic and diluted loss per share calculations assume the conversion of all outstanding shares of preferred stock into shares of common stock using the as-if-converted method as of January 1, 2004 or the date of issuance, if later.

	Year Ended December 31,			Six Months Ended June 30,	
	2002	2003	2004	2004	2005
	(In thousand, except share and per share data)				
				(Unaudited)	
Historical					
Numerator:					
Loss applicable to common stockholders	$ (11,068)	$ (15,250)	$ (24,995)	$ (12,263)	$ (15,699)
Denominator:					
Weighted-average common shares outstanding	1,381,907	1,429,022	1,737,652	1,687,964	1,895,958
Less: Weighted-average unvested common shares subject to repurchase	(456,093)	(202,578)			
Denominator for basic and diluted loss per share applicable to common stockholders	925,814	1,226,444	1,737,652	1,687,964	1,895,625
Basic and diluted loss per share allocable to common stockholders	$ (11.95)	$ (12.43)	$ (14.38)	$ (7.26)	$ (8.28)
Pro forma					
Numerator:					
Net loss			$ (24,995)		$ (15,699)

Denominator:					
Shares used above			1,737,652		1,895,625
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock			13,103,898		16,160,273
Pro forma adjustments to reflect effect of stock dividend			791,210		791,210
Shares used to compute pro forma basic and diluted net loss per share			15,632,759		18,847,108
Pro forma basic and diluted net loss per share			$ (1.60)		$ (0.83)
Historical outstanding dilutive securities not included in diluted loss per share applicable to common stockholders calculation					
Preferred stock	9,978,946	9,978,946	16,160,273	13,525,045	16,160,273
Options to purchase common stock	736,166	683,051	1,368,566	751,906	1,424,393
	10,715,112	10,661,997	17,528,839	14,276,951	17,584,666

Table of Contents

Note 2. License and Collaborative Agreements

In March 2001, the Company entered into various licensing, collaborative and technology transfer agreements with Incyte Corporation (Incyte, formerly Incyte Genomics, Inc.), a related party, to utilize certain intellectual property, technologies and know-how in exchange for milestone and royalty payments. The Company is required to make milestone and royalty payments on net sales of products covered by certain licenses granted under these agreements. Total expense associated with these agreements (including royalties due) was $3.0 million, $1.2 million, $1.3 million, $684,000 and $6,000 for the years ended December 31, 2002, 2003 and 2004 and the six months ended June 30, 2004 and 2005, respectively. All such amounts have been recorded as research and development expense or, in the case of royalties, as cost of product revenues.

Collaborative and Technology Transfer Agreement. Under the Collaborative and Technology Transfer Agreement, the Company agreed to fund a collaborative research and development project relating to specific technologies. The total consideration paid under this agreement was recorded as research and development expense in 2001 on a straight-line basis over the term of the agreement that was terminated in December 2001. Additionally, as part of this agreement, Incyte transferred certain technology and know-how to the Company. The total consideration paid for this technology and know-how was recorded as research and development expense on a straight-line basis through December 31, 2002, which was the end of the estimated useful life of the technology and know-how received.

Patent License Agreement. Incyte granted the Company certain patent rights under a Patent License Agreement. The amount paid to Incyte under this agreement was recorded as research and development expense in 2001, as the Company determined at that time that it did not anticipate receiving benefit from these patent rights in the future. In March 2004, the Company terminated its rights to some of these patents.

LifeSeq Collaborative Agreement. Under the LifeSeq Collaborative Agreement, Incyte has agreed to grant the Company access to certain database products and information. One of the genes in the Onco*type* DX 21-gene panel is licensed under this agreement. Upon commercialization of Onco*type* DX, the Company was required to make a milestone payment and pay royalties each quarter based on net sales of Onco*type* DX. Incyte agreed to defer a portion of the payments originally due during 2002. The deferred amounts, plus interest, were repaid in eight quarterly installments beginning January 1, 2003 and ending October 1, 2004. The remaining consideration is being recorded as research and development expense on a straight-line basis through the end of the access term in April 2005.

Note 3. Specimen Transfer and Collaboration Agreements

The Company has entered into a variety of specimen transfer and collaboration agreements relating to its development efforts. The Company recorded research and development expenses of $240,000, $844,000 and $1.1 million for the years ended December 31, 2002, 2003 and 2004, respectively, and $827,000 and $34,000 for the six months ended June 30, 2004 and 2005, respectively, relating to services provided in connection with these agreements. In addition to these expenses, certain agreements contain provisions for possible royalties from inventions from these collaborations.

Future milestone payments, exclusive of royalty payments, relating to the launch and commercialization of Onco*type* DX total approximately $2.5 million and are payable as follows (in thousands):

	Milestone Payments
January 2006	$ 300
January 2007	300
January 2008	475
January 2009	475
January 2010	475
January 2011	475
Total	$ 2,500

Table of Contents

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 Onco*type*DX. Payments under these agreements for the years ended December 31, 2002, 2003 and 2004 and for the six months ended June 30, 2004 and 2005 were $0, $0, $477,000, $360,000 and $292,000, respectively, and were included in cost of product revenues.

Note 5. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,		June 30,
	2003	2004	2005
			(Unaudited)
Computer equipment and software	$ 688	$ 963	$ 955
Lab equipment	2,022	3,273	4,705
Furniture and fixtures	153	183	190
Leasehold improvements	165	211	332
	3,028	4,630	6,182
Less accumulated depreciation and amortization	(1,740)	(2,514)	(3,172)
	$ 1,288	$ 2,116	$ 3,010

For the years ended December 31, 2002, 2003, 2004 and the six months ended June 30, 2004 and 2005, the Company recorded depreciation and amortization expense of $642,000, $824,000, $1.0 million, $486,000 and $690,000, respectively.

Note 6. 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 cannot prepay any amounts owing under the arrangement until April 2006, at which point it can prepay all, but not part, of the amounts outstanding under the arrangement so long as it also pays a 6% premium on the outstanding principal balance. This premium is reduced to 5% of the outstanding principal balance in April 2007 and 4% of the outstanding principal balance in April 2008.

Table of Contents

As of June 30, 2005, the Company s aggregate commitments under its financing arrangement were as follows (in thousands):

	Annual Payment Amounts (Unaudited)
Years Ending December 31,	
2005 (remainder of the year)	$ 533
2006	1,102
2007	1,102
2008	970
2009	229
Total minimum payments	3,936
Less: interest portion	(676)
Present value of net minimum payments	3,260
Less: current portion of obligations	(777)
Long-term obligations	$ 2,483

Leases

In June 2001, the Company entered into a four-year sublease agreement for its current office and research facility. During 2003, the Company entered into an agreement to extend its sublease through May 31, 2005, wherein monthly rent beginning October 1, 2003, was modified to be $75,000 per month. The Company entered into an additional agreement to extend the term of the sublease agreement through February 28, 2006, wherein monthly rent beginning June 1, 2005 was modified to $40,000 per month. Additionally, 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. The Company is currently in negotiations to directly lease its facilities from the facility owner as of the expiration of the current sublease in February 2006.

Rent expense under all operating leases amounted to $1.4 million, $1.3 million, $911,000, $456,000 and $486,000 for the years ended December 31, 2002, 2003, 2004, and the six months ended June 30, 2004 and 2005, respectively.

Future noncancelable commitments under operating leases at December 31, 2004, were as follows (in thousands):

	Annual Payment Amounts
Years Ending December 31,	
2005	$ 813
2006	122
2007	9
Total minimum payments	$ 944

Note 7. Convertible Preferred Stock and Stockholders Equity (Deficit)

Convertible Preferred Stock

The Company is authorized to issue 101,216,958 shares of preferred stock in series, which shares have been designated Series A, A-1, B, B-1, C, C-1, D, D-1, E and E-1 convertible preferred stock, collectively referred to as preferred stock.

Table of Contents

As of December 31, 2004 and June 30, 2005, the convertible preferred stock consisted of the following (in thousands, except share and per share data):

Series	Designated Shares	Shares Issued and Outstanding	Per Share Liquidation Preference	Carrying Amount	Aggregate Liquidation Preference
Series A	7,935,000	7,935,000	$ 1.00	$ 7,917	$ 7,935
Series A-1	7,935,000		$ 1.00		
Series B	15,675,674	15,675,674	$ 1.85	28,947	29,000
Series B-1	15,675,674		$ 1.85		
Series C	2,252,252	2,252,252	$ 2.22	4,919	5,000
Series C-1	2,252,252		$ 2.22		
Series D	4,073,913	4,073,913	$ 2.30	9,290	9,370
Series D-1	4,073,913		$ 2.30		
Series E	20,671,640	18,543,980	$ 2.82	52,139	52,294
Series E-1	20,671,640		$ 2.82		
	101,216,958	48,480,819		$ 103,212	$ 103,599

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.

Every three shares of Series A, B, C, D and E preferred stock is convertible into one share of common stock upon any of the following events:

with respect to shares held by any stockholder, at any time at the stockholder s option;

automatically upon the closing of an underwritten public offering with aggregate offering proceeds not less than $20.0 million and a per share price not less than $11.40; and

upon agreement of the majority of holders of the outstanding shares of preferred stock voting as a single class, at the then-effective conversion price.

However, if the conversion occurs by reason of an agreement of the majority of holders of the outstanding shares of preferred stock in connection with an underwritten public offering with aggregate offering proceeds either less than $20.0 million or with a per share price less than $11.40, then every three shares of Series E preferred stock will convert into 1.128 shares of common stock. If the Company s initial public offering price of its common stock is less than $11.40 per share, it will be necessary to record a charge relating to the beneficial conversion feature, or BCF, of the Company s series E preferred stock. The Company currently estimates the BCF charge, if recorded, would be approximately $803,000. If the charge is recorded, it would increase the net loss attributable to common stockholders and the net loss per share attributable to common stockholders, but will have no impact on cash and cash equivalents, total stockholders equity (deficit) or net loss in the period in which the initial public offering is completed.

The conversion price of the Company s preferred stock is subject to adjustment to prevent dilution in the event that the Company issues additional shares of preferred stock, common stock, or common stock equivalents at a purchase price less than the then-effective conversion price, provided, however, that without triggering antidilution adjustments,

the Company may issue up to 2,500,000 shares of common stock that are reserved for issuance under the Company s stock option plan to directors, officers, employees, or consultants, or may issue shares in connection with a bona fide acquisition or other strategic transactions that are approved by the Board of Directors.

Table of Contents

Holders of preferred stock are entitled to noncumulative dividends of $0.08, $0.148, $0.177, $0.184 and $0.226 per share per annum for Series A, B, C, D and E, respectively, if and when declared by the Board of Directors (adjusted for any stock splits, stock dividends, recapitalization, or similar events). These dividends are to be paid in advance of any distributions to common stockholders. No dividends have been declared through June 30, 2005.

In the event of a liquidation, dissolution, or winding up of the Company, holders of Series A, B, C, D and E convertible preferred stock shall have a liquidation preference prior to payment to holders of common stock of $1.00, $1.85, $2.22, $2.30 and $2.82 per share, respectively, plus any declared but unpaid dividends. After the payment to the holders of preferred stock, the remaining assets of the Company shall be distributed pro rata to the holders of common stock.

Preferred stockholders are entitled to the number of votes they would have upon conversion of their preferred stock into common stock on the record date.

The convertible preferred stock is classified outside of equity in accordance with Rule 5-02.28 of Regulation S-X because certain features of the Company s Restated Certificate of Incorporation would allow holders of preferred stock to redeem the preferred stock at their option and to trigger liquidation preferences for the preferred stock. The preferred stock constitutes a majority of the outstanding stock entitled to vote, giving the preferred stockholders the ability to amend the Company s Restated Certificate of Incorporation to allow redemption of the preferred stock. A majority of the members of our board of directors is comprised of individuals elected by holders of our preferred stock. Thus, the preferred stockholders have the ability to cause the Company to take corporate actions that would trigger a liquidation preference of the preferred stock. Because the holders of preferred stock can trigger liquidation preferences and redeem the preferred stock at their option, the preferred stock is redeemable upon the occurrence of an event not solely within the control of the Company and is therefore not considered a permanent equity security under Rule 5-02.28.

Common Stock

In 2000, the Company issued 1,345,000 shares of common stock to founders at $0.003 per share, which the Company determined to be the fair value of the common stock upon formation of the Company. The shares sold to the founders are subject to a right of repurchase by the Company subject to vesting, which is over a four year period. There were 456,093, 202,578, zero and zero shares subject to repurchase at December 31, 2002, 2003 and 2004 and June 30, 2005, respectively.

Stock Option Plan

On January 2, 2001, the Company adopted the 2001 Stock Incentive Plan (the Plan), under which incentive stock options and nonstatutory stock options may be granted to employees, officers, and directors of, or consultants to, the Company and its affiliates. Options granted under the Plan expire no later than 10 years from the date of grant. The option price of each incentive stock option shall be at least 100% of the fair value on the date of grant, and the option price for each nonstatutory stock option shall be not less than 85% of the fair value on the date of grant, as determined by the Board of Directors. Options for employees may be granted with different vesting terms from time to time, but not to exceed five years from the date of grant.

As of December 31, 2002, 2003 and 2004, and June 30, 2005, a total of 1,166,666, 1,166,666, 2,500,000 and 2,500,000 shares of common stock have been reserved for issuance under the Plan.

Activity under the Plan is as follows:

		Outstanding Options	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2002	379,033	736,166	$ 0.66
Options granted	(245,500)	245,500	$ 0.99

Options exercised		(283,896)	$	0.66
Options canceled	14,719	(14,719)	$	0.66

Table of Contents

		Outstanding Options	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2003	148,252	683,051	$ 0.78
Options authorized	1,333,333		
Options granted	(906,099)	906,099	$ 2.28
Options exercised		(215,089)	$ 0.66
Options canceled	5,495	(5,495)	$ 0.99
Balance at December 31, 2004	580,981	1,368,566	$ 1.77
Options granted (unaudited)	(118,999)	118,999	$ 3.00
Options exercised (unaudited)		(57,391)	$ 1.02
Options canceled (unaudited)	5,781	(5,781)	$ 1.83
Balance at June 30, 2005 (unaudited)	467,763	1,424,393	$ 1.86

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2004:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Average Years Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.60	50,000	6.07	$ 0.60	48,819	$ 0.60
$0.66	169,571	6.97	$ 0.66	32,367	$ 0.66
$0.69	143,562	7.54	$ 0.69	50,255	$ 0.69
$1.38	520,433	9.39	$ 1.38	35,635	$ 1.38
$3.00	418,333	9.92	$ 3.00		
$3.30	66,667	4.92	$ 3.30		
	1,368,566			167,076	

The weighted average grant date fair value of options granted as of December 31, 2002, 2003 and 2004 was $0.66, $0.78 and $4.98, respectively.

The following table summarizes information concerning outstanding and exercisable options as of June 30, 2005:

	Options Outstanding	Options Exercisable

Exercise Price	Number Outstanding	Weighted Average Years Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.60	50,000	5.58	$ 0.60	50,000	$ 0.60
$0.66	152,134	6.50	$ 0.66	84,694	$ 0.66
$0.69	129,790	7.01	$ 0.69	59,123	$ 0.69
$1.38	490,469	8.91	$ 1.38	67,899	$ 1.38
$3.00	535,333	9.52	$ 3.00	3,667	$ 3.00
$3.30	66,667	4.42	$ 3.30		
	1,424,393			265,383	

The weighted average grant date fair value of options granted as of June 30, 2005 was $8.55.

Deferred Stock-based Compensation

No employee stock compensation expense was reflected in the Company s reported net loss in any period prior to 2004, as all options granted had an exercise price equal to the estimated fair value of the underlying common stock on the date of grant. 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 June 2005

Table of Contents

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 Opinion No. 25. In the six months ended June 30, 2005, an additional $846,000 of deferred stock-based compensation was recorded. The deferred stock-based compensation will be amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. For the year ended December 31, 2004 and the six months ended June 2005, the Company recorded employee stock-based compensation expense of $191,000 and $509,000, respectively.

401(k) Plan

The Company has established a tax-qualified employee savings and retirement plan for which its employees are generally eligible. Under the 401(k) plan, Company employees may elect to reduce their compensation and have the amount of this reduction contributed to the 401(k) plan. The Company does not make matching contributions. The 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code, so that contributions to the 401(k) plan, and income earned on plan contributions, are not taxable to employees until withdrawn from the plan, and so that contributions by the Company, if any, will be deductible by the Company when made.

Stock Options Granted to Nonemployees

The Company grants options to consultants from time to time in exchange for services performed for the Company. During the years ended December 31, 2002, 2003 and 2004, and the six months ended June 30, 2005, the Company granted options to purchase 27,333, 33,000, 8,333 and 5,333 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:

	December 31,			June 30,	
	2002	2003	2004	2004	2005
				(Unaudited)	
Volatility factor	80%	80%	80%	80%	80%
Average risk-free interest rate	4.0%	2.0%	2.4%	2.0%	4.0%
Dividend yield	0%	0%	0%	0%	0%
Expected life of options	10 years	10 years	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, 2002, 2003 and 2004, and the six months ended June 30, 2005, compensation expense related to these options was $36,000, $18,000, $53,000 and $58,000, respectively.

Reserved Shares

As of December 31, 2004, the Company had reserved shares of common stock for future issuance as follows:

Stock option plan	1,949,547
Conversion of preferred stock	16,160,273
	18,109,820

As of June 30, 2005, the Company had reserved shares of common stock for future issuance as follows:

Stock option plan	1,892,155

Conversion of preferred stock	16,160,273
	18,052,428

Table of Contents

Note 8. Related Party Transactions

The Company has entered into various agreements with Incyte Corporation. See Note 2. The Company s Chief Executive Officer and Chairman of the Board is a stockholder of both Incyte and the Company, and until December 31, 2001, was the Chairman of the Board of Incyte. In November 2000, pursuant to a Series A preferred stock purchase agreement, Incyte purchased 1,000,000 shares of the Company s Series A preferred stock at a price of $1.00 per share. In March 2001, pursuant to a Series C preferred stock purchase agreement, Incyte purchased 2,252,252 shares of the Company s Series C preferred stock at a price of $2.22 per share. Under this agreement, Incyte granted the Company the right to cause Incyte to purchase an aggregate of $5.0 million of shares of the Company s common stock upon closing an initial public offering of the Company s shares of common stock, at the initial public offering, price so long as such offering results in gross proceeds to the Company of at least $10.0 million, excluding any amounts received by the Company from Incyte.

Note 9. Income Taxes

As of December 31, 2003 and 2004, the Company had deferred tax assets of approximately $15.5 million and $25.6 million, respectively. Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately $4.6 million, $6.6 million, and $10.1 million during the years ended December 31, 2002, 2003 and 2004, respectively. Deferred tax assets primarily relate to net operating loss and tax credit carryforwards.

Deferred tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2003	2004
Deferred tax assets:		
Net operating loss carryforwards	$ 14,008	$ 23,944
Capitalized costs	1,664	1,546
Research tax credits	821	1,424
Other	74	98
Total deferred tax assets	16,567	27,012
Valuation allowance	(16,567)	(27,012)
Net deferred tax assets	$	$

As of December 31, 2004, the Company had federal and state net operating loss carryforwards of approximately $60.2 million and $57.8 million, respectively, and federal and state research and development tax credit carryforwards of approximately $855,000 and $569,000, respectively. The net operating loss and tax credit carryforwards will expire at various dates beginning in 2021 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 10. Subsequent Events (Unaudited)

2005 Stock Incentive Plan

On September 8, 2005, the Company adopted the 2005 Stock Incentive Plan. 5,000,000 shares of the Company s common stock have been reserved for issuance under the 2005 Plan. Subject to stockholder approval, the 2005 Plan will become effective upon the closing of the Company s initial public offering. 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

Table of Contents

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 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.

Lease

In September 2005, the Company entered into a lease agreement that will apply to the 25,000 square feet of laboratory and office space the Company currently occupies. Under the lease, the Company also leases approximately 23,000 square feet of additional space that the Company expects to first occupy in March 2006. If the Company first occupies space under this new lease in March 2006, the Company will be required to make aggregate rent payments of approximately $4.5 million throughout the entire term of the lease.

Table of Contents

Table of Contents