

Genaissance Pharmaceuticals

Annual Report 2002

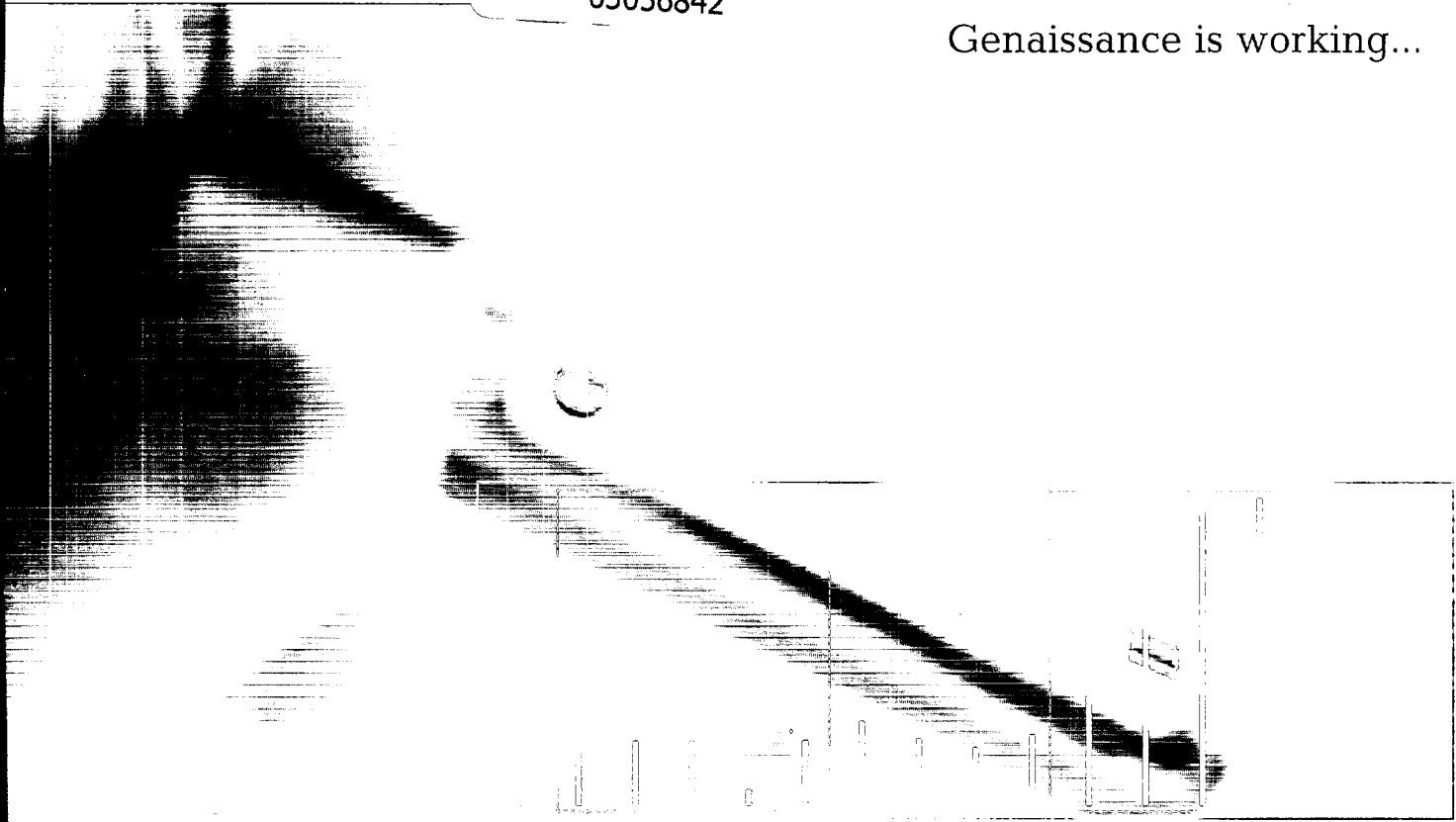
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Genaissance is working...



NON-RESPONDERS

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FINANCIAL

Pharmaceutical Partners	Genaissance Technology Platform	Benefits
<p>Leading pharmaceutical companies access our technology platform and expertise through various partnership programs. Some companies leverage our technology across a broad spectrum of internal drug discovery and marketing efforts. Others apply our technology to the development of a specific drug. In these drug specific partnerships, Genaissance plays an integral part in developing innovative pharmaceutical products.</p>	<p>HAP™ TYPING FACILITY A diagnostics laboratory for the high-throughput genotyping of clinical samples</p> <p>DECOGEN® INFORMATICS SYSTEM A proprietary software package for viewing and analyzing a variety of pharmacogenomic data</p> <p>HAP™ DATABASE A compendium of HAP™ Markers for genes that impact drug response</p> <p>CLINICAL EXPERTISE In-depth experience in clinical-genetic association analyses</p>	<p>By correlating gene variation with drug response, our HAP™ Technology, when combined with our in-depth pharmacogenomics expertise, can provide:</p> <p>The right drug for the right population of individuals, with maximum effectiveness and minimum side effects.</p> <p>More efficient and effective drug development and marketing for pharmaceutical and biotechnology partners.</p> <p>An industry-leading pharmacogenomics company with a future of growth and prosperity.</p>

GENAISSANCE PHARMACEUTICALS is a world leader in the discovery of gene variation and its application to drug discovery, development and marketing. Our HAP™ Technology has the ability to harness the power and potential of personalized medicine by using genomic information to define patient populations with improved drug response.

We discover sequence variation that exists between individuals at the haplotype level to derive HAP™ Markers, which are like genomic bar codes that may accurately predict drug response. Our HAP™ Technology can be used to streamline clinical trials, improve the success rate of drugs in development and maximize the value of drugs already on the market. For example, data from our landmark STRENGTH trials are being incorporated into the product development strategies of a leading diagnostics company.

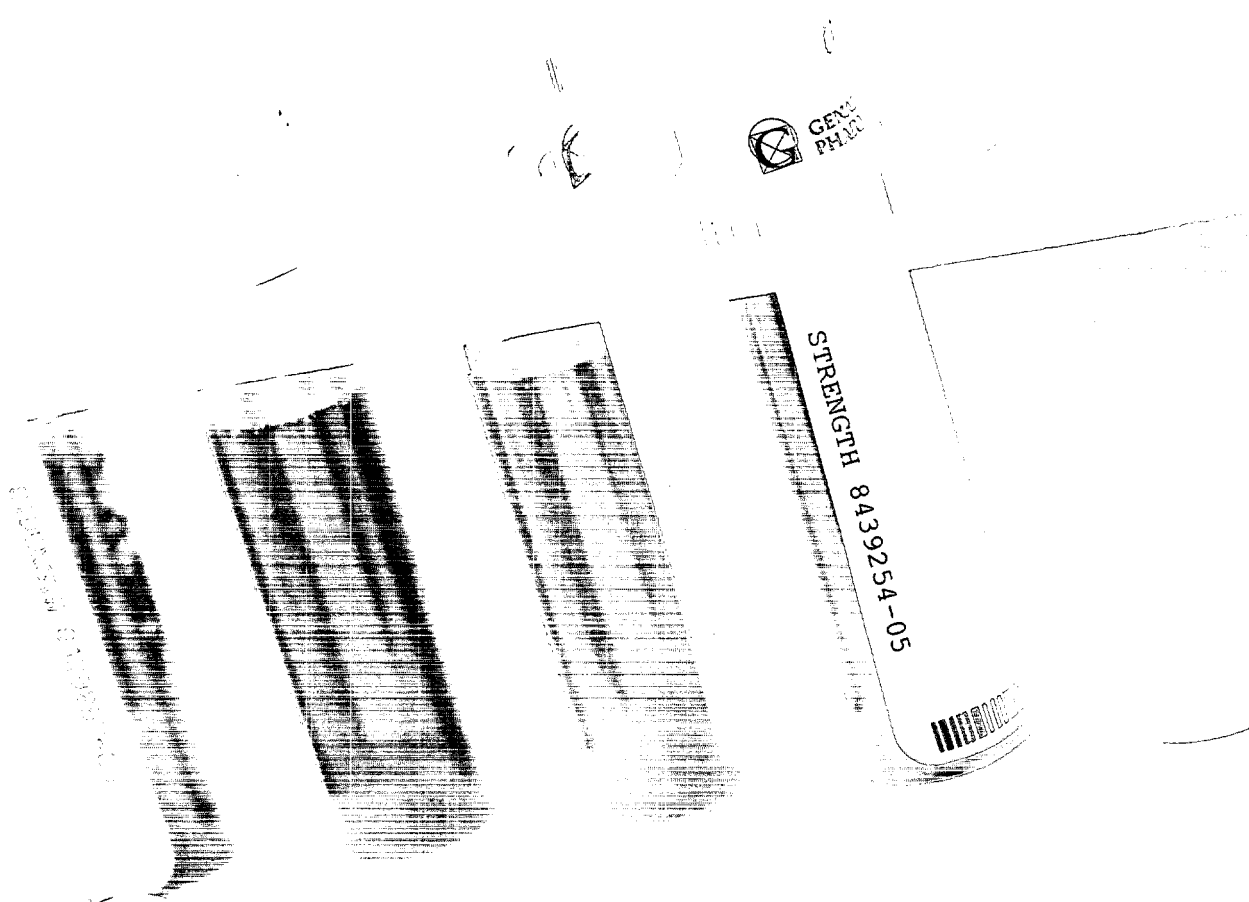
On the cover: From clinical trials through the ongoing development of DNA-based diagnostic tools, our STRENGTH program demonstrates how pharmacogenomics has the potential to revolutionize the way drugs are developed and prescribed.

...to enhance healthcare for patients.

...to improve results for pharmaceutical partners.

...to build value for shareholders.

PHARMACEUTICALS





We're working to predict drug response through genetic variation so that patients will have better results from medications and live healthier lives.

Genaissance's mission since its founding has been to bring safer, more efficacious therapies to market. Today, Genaissance and its partners are even closer to creating a new generation of diagnostic and therapeutic products. Building upon our core competencies, we have developed a suite of products and capabilities that solidify our leadership position in applying genetic variation to drug response. The first product incorporating our HAP™ Technology, a new diagnostic test, could be available within a few years. While Genaissance has remained focused on its mission, the potential of pharmacogenomics to improve healthcare has been increasingly recognized. Most major pharmaceutical companies have already invested in the field. In January 2003, the U.S. Food and Drug Administration committed to clarifying the path to approval for pharmacogenomics tests and products.

HAP™ Typing,
Genotypes in Millions

Number of Associations
Studied Between Genes
and Drug Response

				25,700		
		1.6				
	1.3					
	.42					
					111	460
'00	'01	'02		'00	'01	'02



We're working to improve drug development and marketing for our pharmaceutical partners.

Eight of the world's leading pharmaceutical, diagnostic and biotechnology companies have chosen to partner with Genaissance. These companies have recognized that our HAP™ Technology has the potential to improve significantly drug development and marketing. In fact, every major pharmaceutical company today is seeking a way to bring new drugs to market faster, less expensively, to the right patients and with fewer side effects. Genaissance is working to help them. The diagnostics division of Bayer HealthCare LLC, for example, will leverage the data from our landmark STRENGTH trials to develop a DNA-based diagnostic test for drug selection. Our work with Johnson & Johnson Pharmaceutical Research & Development, our first partner, achieved a key milestone in 2002, another important indication that our HAP™ Technology has an important role to play in the future of drug development at one of the world's premier pharmaceutical companies.

Genaissance Partner	Partner Since
Bayer	2003
Millennium	2003
BD (Becton, Dickinson and Company)	2002
Pharmacia	2002
Biogen	2002
Pfizer	2001
AstraZeneca	2001
Johnson & Johnson PRD	2000



Left to right:
 Gualberto Ruaño, M.D., Ph.D.
 Vice Chairman and
 Chief Scientific Officer
 Kevin Rakin
 President and
 Chief Executive Officer
 Richard S. Judson, Ph.D.
 Senior Vice President,
 Medical Affairs and Informatics
 Gerald F. Vovis, Ph.D.
 Executive Vice President and
 Chief Technology Officer

We're working as a team to build a prosperous and growing company for our employees and shareholders.

During 2002, Genaissance Pharmaceuticals continued to implement a strategy designed to maximize revenue through new partnerships while minimizing the costs of doing business. We achieved success on both fronts. Our management team is squarely focused on creating a strong, successful company for our shareholders, employees and partners. We streamlined our operations in 2002, creating a more efficient, more flexible and responsive organization. Senior management was realigned to create a stronger focus on commercialization. The results of these efforts were immediate: higher revenues, lower operating costs and a significantly reduced cash burn rate that better positions us for long-term prosperity.

Revenue (in millions)			Operating Expenses (in millions)		
		8.1			58.3
	5.3		40.3	38.7	
					Q4: 6.1
					Q3: 6.7
					Q2: 15.2
	.8				Q1: 10.7
'00	'01	'02	'00	'01	'02

"Bayer Diagnostics is very pleased to be working with Genaissance, to utilize their haplotype technology for identification of diagnostic markers and therapeutic targets for individualized medicine. We view the collaboration as a unique opportunity to combine their pharmacogenomics expertise and our marker identification efforts to develop diagnostic tests that will ensure that therapeutic products deliver the maximum benefit to all patients."

WILLIAM WALLEN, PH.D.
SENIOR VICE PRESIDENT OF RESEARCH AND
DEVELOPMENT
BAYER DIAGNOSTICS

Dear Shareholders, Employees and Partners,

I am pleased to report that Genaissance Pharmaceuticals continued to make excellent progress during 2002. While last year was challenging for the Company and, indeed, for our industry as a whole, we enter 2003 in perhaps the strongest position in our six-year history. Today, Genaissance is a leaner and more effective organization, squarely in tune with the needs of the pharmaceutical industry and resolutely focused on commercializing our unique pharmacogenomics platform.

A brief review of our financial results provides evidence of our progress. Annual revenues increased 52% to \$8.1 million during 2002. Perhaps more importantly, our operating expenses for the year decreased 34%. This decrease is attributable to reduced spending on research and development, which is primarily due to completing the majority of the STRENGTH clinical trials in 2001, as well as realizing economies of scale from our maturing infrastructure and a decrease in spending on reagents, payroll and other general expenditures. Our significantly lowered cash burn rate, combined with a \$34 million cash balance, gives us the financial stability to continue to realize near-term revenue growth while we build the foundation for a longer-term strategic role in our industry.

Pharmacogenomics comes of age. Looking back at 2002, one trend seems to stand out as especially encouraging for Genaissance's future: the coming of age of pharmacogenomics. When we founded this Company in 1997, few companies were actively involved in exploring and commercializing the relationship between genetics and drug response. However, the potential of pharmacogenomics has become more widely recognized in subsequent years, and in 2002, the field truly came of age. Most major pharmaceutical companies now incorporate pharmacogenomics into their drug development programs—in fact, several of the largest such companies are our partners.

Acknowledging the potential and importance of the field, the U.S. Food and Drug Administration (FDA) announced, in January 2003, that it would take steps designed to make innovative medical technologies, such as pharmacogenomics, available sooner and to reduce the costs of developing safe and effective medical products—all in a quest to provide better patient outcomes. According to the FDA announcement, pharmacogenomics has "the potential to maximize drug benefits while minimizing toxicity." The FDA will issue guidance on when and how to submit pharmacogenomic information during drug development, which we believe is an important step in easing the regulatory path to commercializing new drugs and further proof that pharmacogenomics is moving closer toward inclusion in mainstream drug development.

"Biogen is very pleased to be working with Genaissance, a company at the forefront of applying gene variation information to drug development. We view the collaboration as an opportunity to build on our leadership in using new technologies to understand the heterogeneity of human disease and ensure that our drugs deliver maximum benefit to patients."

MICHAEL GILMAN, PH.D.
SENIOR VICE PRESIDENT OF RESEARCH
BIOGEN

As a leader in the field of pharmacogenomics, Genaissance regularly meets with the FDA on policy issues. We expect to continue to play an important role in educating regulatory authorities on the practical aspects and utility of this field, with the goal of helping them establish policies and guidelines that are beneficial to the entire healthcare system.

Partnering with leaders. Having helped to lead the way in the field, Genaissance is well positioned to capitalize on the maturation of pharmacogenomics. Our strategy of partnering with leading pharmaceutical and biotechnology companies gained momentum during the past year, with four new agreements signed in the past few months alone. Our deal with Bayer HealthCare, in particular, represents a very important milestone. This agreement commercializes the associations generated from our STRENGTH trials with one of the world's leading diagnostic companies. As many of our shareholders know, STRENGTH was our landmark clinical trial comparing three of the leading statin drugs. Using our HAP™ Technology, Genaissance found genetic markers predictive of drug response in this \$18 billion class of cholesterol-lowering drugs. With this new agreement, the important data from the STRENGTH trials will be combined with Bayer's clinical samples from its outcomes trials. The goal is to develop diagnostic tests that determine adverse drug response and efficacy response to an existing drug class as well as to newly developed drug products. Genaissance will receive royalties on pharmaceutical and diagnostic products resulting from this partnership, while Bayer will pay all subsequent costs of development and commercialization of products. In collaboration with our partners, we expect to have products available within a few years, which we believe will begin a unique franchise in the area of drug response.

Our 2002 partnership with Pharmacia & Upjohn Company is a drug-specific collaboration. Pharmacia has licensed our *DecoGen*® Informatics System and we are applying our HAP™ Technology to its clinical trial samples. Our 2003 agreement with Millennium Pharmaceuticals highlights the fact that, in addition to working with top pharmaceutical companies, our commercialization plans include partnering with leading biopharmaceutical firms. In this multi-year agreement, Millennium has licensed our HAP™ Technology for use in its internal and partnered drug discovery and development programs. Millennium and Genaissance share a common mission—the commercialization of personalized medicine—and Millennium has an excellent track record of using leading-edge technology for new product development. We believe this collaboration is an excellent fit for both companies.

Another recently announced partnership is with Becton, Dickinson and Company, or BD, as the company is now known. BD is providing equipment, reagents and training in exchange for future royalty payments. With this agreement,

"We share the Genaissance vision that the prediction of drug response by breakthrough genetic-based diagnostics will be the future. Our agreement to provide Genaissance with our proprietary BDProbeTec ET platform and Strand Displacement Amplification technology reflects our belief that Genaissance's unique *HAP*[™] Technology places them in a strong position to create that future."

MICHAEL C. LITTLE, PH.D.
WORLDWIDE BUSINESS LEADER OF
MOLECULAR DIAGNOSTICS
BD DIAGNOSTIC SYSTEMS

we now have a platform, which exists at diagnostic sites worldwide, that has the potential of delivering a pharmacogenomics-based test in less than one hour at an affordable price. This agreement adds another aspect to our service offering, and we expect to use this platform for our pharmaceutical clients' validation studies and diagnostic tests to support the marketing of their drugs.

We registered solid progress during 2002 with our existing partners, as well. I am particularly pleased about a milestone that was achieved in our collaboration with Johnson & Johnson Pharmaceutical Research & Development (J&J PRD), a division of the Johnson & Johnson family of companies. This milestone reflects the important progress that has been made through our partnership and offers solid proof that our *HAP*[™] Technology can be used to identify meaningful associations between genetic variation and clinical observations. In the two years since this partnership was launched, we have developed close and productive working relationships with our colleagues at J&J PRD, and we look forward to continuing to work closely together to further integrate the results generated from our alliance into pharmaceutical product development.

I am also pleased that Pfizer has extended its agreement with us through August 2004, allowing Pfizer to gain non-exclusive access to selected portions of our *HAP*[™] Database.

Operational improvements. In addition to progress on the partnership front, we made significant headway last year in realigning our cost structure to enable us better to execute our short- and long-term strategies. We took the difficult, but necessary, step of reducing our work force by 20%. At the same time, we continue to add industry-knowledgeable sales and marketing professionals to help us continue to strengthen our commercial profile. To sharpen the Company's focus on commercialization, the Board of Directors realigned senior management roles. I was appointed CEO, in addition to remaining President, with responsibility for all business and operating functions. Gualberto Ruaño, M.D., Ph.D. was named Vice Chairman and Chief Scientific Officer. Gualberto will focus on developing new market opportunities and working with government and healthcare agencies for additional applications of our *HAP*[™] Technology.

To drive both near-term and long-term revenues, Genaissance focused on developing new markets during 2002. For example, we identified government and academic entities as promising markets for our technology. An early result of this focus is our agreement with Wayne State University (WSU) to support WSU's research contract with the National

"During 2002, Genaissance made important progress in positioning itself to capitalize on the exciting potential of pharmacogenomics. New partnerships, a realigned management team and further validation of Genaissance's unique technology platform all combined to make this a very significant year for the Company."

JÜRGEN DREWS, M.D.
CHAIRMAN
GENAISSANCE PHARMACEUTICALS

Institute of Child Health and Human Development's Perinatology Research Branch, which is located at the WSU School of Medicine in Detroit, Michigan. We continue to make progress in Japan, the world's second largest pharmaceutical market, where INTEC W&G Corporation serves as our sales representative.

2003 and beyond. Looking ahead, we will continue to seek new partnerships to commercialize our unique and compelling pharmacogenomics platform. Our strategy for building value has near- and longer-term components. In the near term, we will seek to drive revenue through out-licensing our HAP™ Technology. We will continue to build the foundation for revenues from product royalties and related testing fees by developing, with our partners, drug response pharmacogenomics tests. In the longer term, our goal is, through partnerships, to have our technology included in the development of more efficacious and safer therapies. We believe our strategy is well on the path to success.

Thus, we enter 2003 propelled by strong momentum, including a broadening acceptance of pharmacogenomics; five agreements in the past few months alone; an improving financial position; and a focused, proven strategy for growth. From our founding six years ago, our mission has never wavered, and it remains as relevant today as ever: to integrate our HAP™ Technology into pharmaceutical product development and marketing to ensure that the next generation of FDA-approved therapeutics includes our genetic markers. We made substantial progress last year and are on our way to making 2003 an even more significant year for Genaissance.

As always, our accomplishments are the result of the hard work, ingenuity and dedication of our employees and board, and the support of our partners, who once again have demonstrated their commitment to delivering the full benefits of personalized medicine.



Kevin Rakin
President & Chief Executive Officer

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

(MARK ONE)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2002

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NO. 000-30981

GENAISSANCE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

06-1338846
(I.R.S. Employer Identification No.)

Five Science Park
New Haven, Connecticut
(Address of principal executive offices)

06511
(Zip Code)

Registrant's telephone number, including area code: (203) 773-1450

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

Securities registered pursuant to Section 12(g) of the Act: COMMON STOCK, \$.001 PAR VALUE
(Title of each class)

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

The aggregate market value of voting Common Stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) on June 30, 2002 was \$26,843,669 based on the last reported sale price of the Common Stock on the Nasdaq consolidated transaction reporting system.

Number of shares of the registrant's class of Common Stock outstanding as of March 28, 2003: 22,846,897.

Documents Incorporated By Reference:

Items 10, 11, 12, 13 and 15 of Part III (except for information required with respect to our executive officers which is set forth under "Executive Officers" in Item 1A of Part I of this report) have been omitted from this report, since we expect to file with the Securities and Exchange Commission, not later than 120 days after our fiscal year end, a definitive proxy statement. The information required by Items 10, 11, 12, 13 and 15 of this report, which will appear in the definitive proxy statement, is incorporated by reference into Part III of this report.

ITEM 1. BUSINESS

Company Overview

Our goal is to create personalized medicines through the integration of pharmacogenomics into drug development and marketing. Pharmacogenomics is the study of how an individual's genetic inheritance affects the body's response to a drug. We discover inherited differences, or genomic markers, that exist in human genes. We use our technological capabilities and methods and our clinical genetics development skills to identify the genomic markers that appear to define a patient population that responds best to a medication and has a superior safety profile. We market our technology and our genomic markers to the pharmaceutical and biotechnology industry as a means to improve the development, marketing and prescribing of drugs.

We were incorporated in Delaware on February 22, 1992 and changed our name to Genaissance Pharmaceuticals, Inc. on March 18, 1997. Our principal executive offices are located at Five Science Park, New Haven, Connecticut 06511. Our telephone number is (203) 773-1450. Our website is located at <http://www.genaissance.com>.

Industry Overview

Development and Marketing of Drugs

The pharmaceutical, biotechnology and healthcare industries face intense pressure to become more productive and deliver more cost effective healthcare. Two of the pharmaceutical and biotechnology industry's most challenging issues are the high cost and low success rate of developing drugs and the need to differentiate approved drugs in highly competitive markets. At the same time, healthcare providers and payers are spending a growing proportion of their resources on prescription drugs.

The drug development process is costly and subject to a high failure rate. The average cost of developing a drug is estimated to be \$500 million, including the cost of unsuccessful drug candidates. Even with recent technological advances, including advances in areas such as genomics, the failure rate of clinical trials remains very high. In the United States, only one in five drug candidates that enters clinical trials reaches the market. Seventy percent of the drug candidates that enter clinical trials successfully complete phase I, 33% complete phase II, 25% complete phase III and only 20% achieve regulatory approval. The decision to enter phase III, the most costly phase of clinical trials, is generally based upon the results obtained from the limited number of individuals, often fewer than 200, typically studied in phases I and II. The typical patient population in phase III is between 1,000 and 5,000 individuals, and the average amount of money spent in a single phase III clinical trial is estimated to be greater than \$40 million.

Approved drugs often face intense competition. The period of market exclusivity for the first drug in a new therapeutic class is typically much shorter today than it was a few years ago. Consequently, marketing expenditures have increased rapidly as companies attempt to maintain or increase market share. For example, in 2001, U.S. based pharmaceutical companies spent over \$19 billion on promotional activities, including sales representatives, product samples and journal advertising. Marketing departments are also under pressure to maximize the revenue generated from approved products in order to meet corporate-wide revenue and earnings goals. In addition, the major pharmaceutical companies, which have reported an average increase in earnings of 14% over the past five years, now face competition from generic drugs for several of their blockbuster drugs that generated over \$40 billion in sales in 2001. Thus, in order to maintain revenue growth rates and profitability, pharmaceutical companies must both improve the success rate of clinical trials and differentiate their drugs in a crowded market place.

According to the National Institute for Health Care Management, sales of prescription drugs in the United States increased 18.2% in 2001 from \$148.2 billion in 2000 to \$175.2 billion. Retail spending

on outpatient prescription drugs has nearly doubled since 1997. In an attempt to contain the rising cost of drug expenditures, healthcare providers and payers face the difficult task of deciding which drugs should be prescribed to specific patients and are suitable for reimbursement. Healthcare providers make these decisions using medical outcome studies and economic benefit factors but they do not have any knowledge of which individual patients are most likely to benefit from a specific drug, if at all. Thus, healthcare providers and patients would benefit from using drugs that are targeted for a patient population that would have the best drug response and safety profile, and, thus, allow for more appropriate and safer intervention.

Population Genomics

The medical community generally acknowledges that most drugs work more effectively for some patients than for other patients. The pharmaceutical and biotechnology industry often poorly understands this variability in patient response. Consequently, pharmaceutical and biotechnology companies may unnecessarily discontinue further drug development, fail to obtain regulatory approval for promising drug candidates, or, even if a drug obtains approval, be unable to market an approved drug effectively or to obtain approval for third party reimbursement.

Scientists have known for a long time that genomic differences influence how patients respond to drugs. However, pharmaceutical and biotechnology companies generally have not considered genomic differences between patients in developing and implementing clinical trials or in the marketing of approved drugs. If, in clinical trials, pharmaceutical and biotechnology companies were able to use genomic markers to identify patient populations that would have different drug responses, they could improve the drug development and marketing process. For example, pharmaceutical and biotechnology companies could use the genomic markers, which are identified in phase I and phase II clinical trials as being predictive of a clinical outcome, to determine the size of the patient population that would likely benefit from the drug under development. They would also know the size of the clinical group needed for a phase III clinical trial to obtain statistically significant data to support the clinical development program. In addition, if pharmaceutical and biotechnology companies could identify the patients most likely to have a side effect, they could more closely monitor these patients or eliminate them from participating in clinical trials and receiving the drug and, hence, increase the safety profile of a drug. The pharmaceutical and biotechnology companies would, therefore, have a better understanding of the cost required to complete the development of a drug and the likely economic return on their investment before proceeding to a phase III clinical trial. In addition, if pharmaceutical and biotechnology companies could use genomic markers to predict a drug response, they would be able to improve the marketing of their drugs by identifying those patient populations for which particular drugs are likely to be most effective with the least likelihood of having an adverse reaction. Furthermore, healthcare providers and payers would likely benefit economically from predictive information that would enable a physician to prescribe the most appropriate and safest medication at the earliest possible time.

Population genomics is the analysis of genomic variation within groups of people. The genomic blueprint each person inherits from his or her biological parents determines differences, such as height, hair color and eye color. As scientists better understand variation at the molecular or genomic level, they are more certain that an individual's response to a drug is dependent upon that individual's unique DNA sequence and that more than one gene is probably involved in a drug response. Scientists know that every drug generally interacts, directly and indirectly, with a variety of different proteins produced by different genes. Therefore, in order to predict a specific drug response, scientists must analyze genomic variation in multiple genes.

Single Nucleotide Polymorphisms and Haplotypes

At the DNA level, genomic variation occurs mainly as a result of variation at a single position in the DNA sequence, commonly referred to as a single nucleotide polymorphism or SNP. Geneticists historically studied genetic variation by analyzing the inheritance of traits within an extended family. Classical population geneticists coined the term haplotype to describe the physical organization of genetic variation as it occurs in an individual. The haplotype is the standard for measuring genetic variation. At the molecular level, a haplotype consists of multiple, individual SNPs that are organized into one of the limited number of combinations that actually exists as units of inheritance in humans. Each haplotype contains significantly more information than individual, unorganized SNPs. As a result, clinicians need fewer patients to define a patient population with a different drug response if they use haplotypes rather than individual, unorganized SNPs.

In October 2002, an international consortium, composed of non-profit biomedical research groups and private companies in Japan, the United Kingdom, Canada, China and the United States, initiated an effort to create a genome-wide haplotype map. This new venture is aimed at speeding the discovery of genes that are related to common illnesses, such as asthma, cancer, diabetes and heart disease. The consortium expects that the International HapMap Project, which will use as its starting material the more than 2.8 million SNPs that are already in a public database, will take three years to complete at an estimated cost of \$100 million. The resulting haplotype map could contain anywhere from 300,000 to 600,000 SNPs. Using this genome-wide haplotype map, researchers may only identify a genomic region that is involved in causing a disease or drug response rather than the specific gene that is responsible. Researchers are, thus, likely to need a database of gene haplotypes to determine which of the genes that are contained within the identified genomic region is actually the gene responsible for causing the disease or drug response.

Through the use of gene haplotypes, together with sophisticated software programs, drug developers could identify, with statistical accuracy in a small population of the size commonly seen in phases I and II of clinical trials, the genomic variation that defines different patient populations with different drug responses and, therefore, make better informed decisions on whether or not to enter phase III clinical trials. In addition, defining the patient population with the desired clinical outcome would enable drug developers to improve the marketing of their drugs by identifying those patients for whom particular drugs are likely to have the best safety profile and be most effective. Furthermore, healthcare providers and payers would likely benefit economically from predictive information that would enable a physician to prescribe the appropriate medication at the earliest possible time.

Regulatory Environment

On January 31, 2003, the FDA announced a broad initiative, whose purpose is to help make innovative medical technology available sooner and to reduce the costs of developing safe and effective medical products while maintaining the FDA's traditional high standards of consumer protection. The FDA included, in its initiative, the use of pharmacogenomics during drug development. The FDA indicated that within six months the agency would issue draft guidance on when and how to submit pharmacogenomic information to the FDA during drug development. The FDA said that this guidance would facilitate the exploratory use of pharmacogenomic screening during drug development and would clarify when such information would be considered part of the evaluation of drug safety. In addition, the FDA stated that the agency would hold a workshop in 2003 on issues that are involved in the co-development of a pharmacogenomic test and a drug and that within 18 months the agency would issue guidance on the regulatory pathway for such combinations through the agency's Center for Drug Evaluation and Research and the Center for Devices and Radiological Health.

The Genaissance Solution

We have developed a combination of technologies and expertise, which we call our *HAP*[™] Technology, that allows population genomics to be integrated into the development, marketing and prescribing of new and existing medicines.

The key components of our *HAP*[™] Technology are:

- a database of highly informative, proprietary measures of genomic variation, or haplotypes, which we call *HAP*[™] Markers, for pharmaceutically relevant genes;
- a proprietary informatics system, which we call *DecoGen*[®], including unique algorithms, for defining patient populations with different drug responses;
- a cost effective, efficient process for measuring genomic variation in clinical DNA samples, which we call *HAP*[™] Typing; and
- clinical genetics development skills.

We designed our *HAP*[™] Technology to permit pharmaceutical and biotechnology companies to use population genomics in a variety of ways for drug development and commercialization.

Drug Development. We designed our *HAP*[™] Technology to improve the success rate of drugs in clinical trials by:

- assessing efficiently the genomic variation among the patients involved in a clinical trial, thereby permitting pharmaceutical and biotechnology companies to incorporate genomic variation information into all decisions required during the course of a clinical trial;
- creating better informed, or “smarter,” clinical trials through the design of protocols, which result in the inclusion of those patients most likely to benefit, with a superior safety profile, from the proposed therapeutic product;
- facilitating earlier “go/no-go” decisions on whether to proceed to the next phase of clinical trial testing, which should result in a more efficient use of clinical resources; and
- reducing the size and, hence, the cost of late-stage clinical trials by enrolling a group of patients, who are most likely to respond to a drug and are least likely to suffer an adverse reaction.

Drug Marketing and Prescribing. We also designed our *HAP*[™] Technology to help maximize the value of an approved drug by:

- identifying which of our *HAP*[™] Markers define the patient population with the best response and with a superior safety profile;
- integrating genomic variation information into marketing strategies to sustain and enhance a market leading position or to address problems such as poor market penetration, competitive pricing issues, safety, risk of therapeutic substitution, and limited patent life; and
- targeting new markets and obtaining approval for new indications.

Our *HAP*[™] Technology could also be useful for improving the drug discovery process through the selection and validation of drug targets. In addition, pharmaceutical and biotechnology companies could incorporate data obtained during clinical trials into the drug discovery process to develop second-generation drugs. If widely adopted, our *HAP*[™] Technology could enable the healthcare system to personalize treatment based upon an individual's unique genome.

Our Strategy

Our strategy consists of the following:

To generate current revenues from commercializing our HAP™ Technology in various markets. The specific revenue sources would include:

- license fees from granting access to our database of HAP™ Markers for pharmaceutically relevant genes;
- HAP™ Typing fees for measuring the genomic variation present in DNA samples;
- Study fees for identifying the genomic markers responsible for defining populations with different drug response or different traits; and
- revenues from homebrew diagnostic tests, which we offer that define populations with different drug response or different traits.

The different markets include:

- pharmaceutical companies, including those in regional markets, such as Japan;
- biotechnology companies;
- diagnostic companies;
- government and academic groups; and
- consumer markets, such as nutraceuticals.

To establish contractual rights for royalties from the sale of drugs and diagnostic tests. The revenue sources would include developing, with partners, drug response pharmacogenomic tests from the intellectual property created in our HAP™ Partnership program or in our internal programs. Under our current strategy, and for the foreseeable future, we do not expect to develop or market pharmaceutical or diagnostic products on our own. However, we seek royalties from the sale of drugs and diagnostics, which use our HAP™ Markers in a diagnostic test that:

- defines drug safety or efficacy or
- is sold in combination with the use of a drug.

Our commercialization programs include the following:

Commercialize our HAP™ Technology through our HAP™ Partnership program. We have developed a program intended to provide pharmaceutical and biotechnology companies access to our HAP™ Technology and our clinical genetics development expertise throughout each phase of drug development and marketing. Potential partners are offered access to our proprietary HAP™ Markers, our DecoGen® Informatics System, our HAP™ Typing facility, which we use to measure HAP™ Markers from individual patient samples, and our clinical genetics development expertise. In return, we seek annual subscription fees and payments for our collaborative contributions to specific drug development or marketing projects and for our HAP™ Typing services. In addition, we expect license fees, as well as milestone and royalty payments, for the commercial use of our HAP™ Markers. While we expect to retain all intellectual property rights in HAP™ Markers discovered during the partnership, we offer our partners an option to obtain multiple exclusive licenses for the use of particular HAP™ Markers for the development of therapeutic and diagnostic products within specified drug classes and for particular disease indications. We currently have a HAP™ Partnership program with six pharmaceutical and biotechnology companies (AstraZeneca UK Limited; Biogen, Inc.; Johnson & Johnson Pharmaceutical Research & Development, a division within the Johnson & Johnson family of companies; Millennium Pharmaceuticals, Inc.; Pfizer Inc.; and Pharmacia & Upjohn Company). We are in discussions and

negotiations with additional pharmaceutical and biotechnology companies to enter into our HAP™ Partnership program, including pharmaceutical companies in such regional markets as Japan, where we are using Intec Web and Genome Informatics Corporation as our sales representative. We cannot, however, assure you that we will be successful in these discussions and negotiations.

Commercialize with partners the intellectual property that we develop with our HAP™ Technology. We currently have two programs from which we expect to have intellectual property to commercialize with our partners.

STRENGTH Trials (Statin Response Examined by Genetic HAP™ Markers). We applied our HAP™ Technology and our clinical genetics development skills to the statin class of drugs, which doctors use to treat patients with high cholesterol and lipid levels and who are, therefore, at risk for cardiovascular disease. This market is highly competitive with multiple approved products seeking to gain increased market share. Currently, the market is approximately \$18 billion worldwide and experts estimate that the market is growing at the rate of about 20% per year.

We examined five statins in our two prospective STRENGTH clinical trials. The goal of these two trials was to identify which of our HAP™ Markers define a patient population that has the best therapeutic response to one or more of these statins with a superior safety profile. In April 2001, we began enrollment for the first of our two STRENGTH trials, in which patients were randomized and then enrolled into one of four treatment arms, in which a patient was treated with one of four statins. The four drugs used were atorvastatin (sold by Pfizer Inc. as Lipitor®), cerivastatin (sold by Bayer AG as Baycol®), pravastatin (sold by Bristol-Myers Squibb Company as Pravacol®) and simvastatin (sold by Merck as Zocor®). Following the withdrawal of cerivastatin from the market in August 2001, we discontinued treating all of the patients who were taking this product. In October 2001, we began enrollment in our second STRENGTH trial, in which enrolled patients received lovastatin (sold by Merck as Mevacor®). The trial protocol for both STRENGTH trials was to treat each patient for eight weeks with the lowest dose recommended on the drug label followed by then treating each patient for eight weeks with the highest dose recommended on the drug label. At least 149 patients were enrolled into each treatment arm. Enrollment was completed for STRENGTH I in July 2001 with the last patient receiving the last examination in November 2001. Enrollment was completed for STRENGTH II in November 2001 with the last patient receiving the last examination in March 2002.

In January 2003, we signed an agreement with Bayer HealthCare LLC to commercialize exclusively the diagnostic rights and non-exclusively the drug product development rights from our STRENGTH trials. We are in discussions with pharmaceutical companies to commercialize additional drug product development and marketing rights from these trials, but we cannot assure you that we will be successful in these discussions.

CARING Study (Clozapine HAP™ Marker Discovery Study). In February 2002, we initiated a study designed to identify which of our HAP™ Markers define the patients who are most likely to develop agranulocytosis, a potentially life-threatening depletion of white blood cells, if treated with clozapine. Clozapine, which is no longer under patent protection, is a highly effective therapeutic for treating certain patients with schizophrenia. During the first six months of treatment with clozapine, a patient must undergo weekly blood monitoring, a requirement that results in poor patient compliance. We believe that clozapine's third-line therapy status and the requirement for repeated blood testing are the primary reasons that the market share for all clozapine products is only approximately \$350 million in the United States. Sales of antipsychotic drugs in the United States reached an estimated \$5.2 billion in 2000 and are expected to exceed \$8 billion by 2005. As of March 3, 2003, we have obtained blood samples from 23 patients who took clozapine and developed agranulocytosis. We have also obtained blood samples from 12 patients who took clozapine and developed granulocytopenia (a significant reduction in the number of white cells) as well as 21 matched control samples from patients who took clozapine without experiencing any significant decrease in white blood cell counts.

We plan to use these patient samples with our *HAP*[™] Technology to identify the *HAP*[™] Markers that define the population most likely to develop this adverse reaction. If we are successful in identifying these genomic markers, we plan to seek a suitable partner to commercialize these *HAP*[™] Markers either through a diagnostic test or a diagnostic test associated with a drug.

Commercialize our HAP[™] Technology in numerous markets. We are now offering our *HAP*[™] Technology, including our sequencing and genotyping services, to potential partners in additional markets, including research groups in government and academia, and to companies involved in the sale of nutraceuticals.

Pursue strategic acquisitions. We continually evaluate opportunities that may provide us with, among other things, intellectual property, key personnel, capabilities that could augment our recurring revenues or technologies that will enhance and complement our *HAP*[™] Technology. From time to time, we intend to pursue acquisitions, which we believe will meet these goals.

Asthma Clinical Study as a Proof of Principle

To demonstrate how the pharmaceutical and biotechnology industry and healthcare providers could use our *HAP*[™] Technology, we conducted a clinical study to determine whether we could use *HAP*[™] Markers or SNPs to define an asthma patient population that responded to the drug albuterol (sold by GlaxoSmithKline as Ventolin[®]), a standard treatment for persons with asthma. We conducted the study in collaboration with Dr. Stephen Liggett, a member of our scientific advisory board and a professor of medicine at the University of Cincinnati Medical Center. We examined genomic variation in the target of the drug, the β_2 -adrenergic receptor (β_2 -AR). Dr. Liggett recruited 121 asthmatic individuals for clinical treatment and made a large number of standard pulmonary measurements, before and after he treated the patients with albuterol. The response to the drug differed significantly from patient to patient and the drug was clinically effective in only 40% of these patients as measured by generally accepted clinical criteria. Dr. Liggett and his staff drew blood samples and extracted the DNA. We did the *HAP*[™] Typing and, using our *DecoGen*[®] Informatics System, identified specific pairs of *HAP*[™] Markers in the β_2 -AR receptor gene that were carried by patients that exhibited a positive drug response and specific pairs of *HAP*[™] Markers that were carried by patients that exhibited a poor drug response. By contrast, no individual SNP was found to have such predictive power in this study. This study, which was similar in sample size typically used for a phase II clinical trial, showed that a patient's response to albuterol correlated, in a statistically significant manner, with specific *HAP*[™] Markers.

We published a more detailed description of this study in a peer reviewed scientific journal in September 2000. In February 2003, we received notice from the U.S. Patent and Trademark Office of its allowance of a patent application filed by us, which contains claims based on these findings. In addition, we worked with a company that has a FDA approved, DNA-based diagnostic platform and verified the SNP assays they developed for defining the predictive *HAP*[™] Markers. This proof of principle diagnostic assay and our clinical study demonstrate that a pharmacogenomic test for drug response can be developed for point of care use with technology currently available.

Our Technology

Overview

Our process for discovering *HAP*[™] Markers eliminates the need, which is inherent in family-based approaches, to find and then test large numbers of families or related individuals to determine genomic variation. Initially, we discover individual SNPs by high-throughput sequencing of DNA samples of unrelated and related individuals that are representative of the individuals who constitute the major pharmaceutical markets of the world. We use our proprietary algorithms to organize the SNPs into

HAP[™] Markers. Using these algorithms, we found that the number of actual *HAP*[™] Markers per gene is significantly less than the theoretically large number of ways in which SNPs could be organized.

Our *DecoGen*[®] Informatics System contains a number of components. Our *HAP*[™] Database contains our *HAP*[™] Markers, including information about their sequence, frequency and distribution. Our *DecoGen*[®] Informatics System also contains a proprietary collection of algorithms and a search engine that correlates a patient's *HAP*[™] Markers with a particular response to a drug. To handle large amounts of information, we developed a proprietary tool, which we call RuleFinder[™], that allows us to identify rapidly potential associations between clinical endpoints and genetic variation. Then using standard analytical tools, we have been able to determine with statistical accuracy the correlation between *HAP*[™] Markers and drug response in a small population of the size commonly seen in phase I and phase II of a clinical trial.

HAP[™] Typing is our process for measuring which *HAP*[™] Marker pairs are present in a patient's DNA sample. Our *HAP*[™] Typing facility uses proprietary software, robotics and Sequenom's MassARRAY[™] platform to determine, on a high-throughput basis, which two *HAP*[™] Markers for a gene are present in a patient's DNA sample. We integrate the resulting data into our *DecoGen*[®] Informatics System to search for a correlation with a patient's drug response. We have a customized 8,000 square foot facility, dedicated to *HAP*[™] Typing, which became licensed to do diagnostic testing in April 2002 by the Connecticut Department of Public Health under the U.S. Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The following outlines the components of our *HAP*[™] Technology and how we use our *HAP*[™] Technology to define a patient population with a specific drug response.

Gene Selection

Our goal is to discover *HAP*[™] Markers for pharmaceutically relevant genes. We prioritize these genes for *HAP*[™] Marker discovery based upon the needs of our *HAP*[™] Partnership program partners. We obtain genomic information relevant for gene selection from publicly available sources and from proprietary databases. We have discovered *HAP*[™] Markers for genes that are, or will likely become, drug targets; are associated with drug target pathways; are involved in how drugs modify cell communication or regulate other genes; and are involved in the metabolic process by which the body absorbs a drug and breaks it down.

Index Repository

We constructed an Index Repository, a collection of diverse DNA samples, to discover the SNPs that are present in genes. We designed our Index Repository to contain genomic information that would be representative of the people who constitute the major pharmaceutical markets of the world; to aid in the quality control analysis of the SNPs we discover; and to facilitate the organization of SNPs into *HAP*[™] Markers.

To build our Index Repository, we recruited over 650 individuals whose parents and grandparents came from specified geographical regions. We obtained personal information from each individual, including sex, date of birth, and general medical information, as well as a detailed family history and drew blood samples so that we could create continually multiplying cells from the white cells present in the blood. The resulting cells, called permanent cell lines, provide us with a supply of DNA from which to discover SNPs. We store frozen samples of each cell line at multiple locations to ensure that all of these cell lines are available in the future. To supply sufficient DNA for the production process, we routinely grow the cell lines in our cell culture facility. We employ quality control procedures that permit each DNA sample to be unambiguously matched to its corresponding cell line. We store all of the information about a cell line in our proprietary *HAP*[™] Database that is a component of our *DecoGen*[®] Informatics System.

Discovering SNPs

We use a subset of our Index Repository to discover SNPs. We employed principles of population statistics to determine the minimum number of unrelated individuals that we needed to have a 99% probability of detecting a SNP or *HAP*[™] Marker that occurs in at least 5% of the general population or in at least 10% of a population from a specific geographical region.

We sequence individual samples of DNA so that we can accurately determine the frequency of a SNP in the population. Our procedure allows us to detect SNPs that are present at lower frequencies than if we were to analyze a mixture of DNA from different individuals, as is done by some companies. We sequence 93 individual, human DNA samples, or 186 individual genomes, from our Index Repository in the following genomic regions for each selected gene: the region responsible for controlling when a gene is active, the control region; the regions containing coding information that is found in the protein product of the gene, the coding regions; the boundaries between the genomic regions containing coding information and those interspersed regions that do not contain coding information, the non-coding regions; and the region at the end of a gene immediately after the last region containing coding information.

Our sequencing process is highly automated, from picking the regions to be sequenced through loading the samples onto one of our sequencing machines. We have also developed a proprietary laboratory information management system to track genes as they progress through the production pipeline. We use this system to monitor the overall quality of data we produce to ensure that the sequencing process is operating according to our established standards. The sequence information undergoes two forms of quality control analysis. We use electronic procedures and established population genomic principles to identify and validate that a SNP exists at a given position.

HAP[™] Markers and *HAP*[™] Database

Geneticists use the term haplotype to describe how SNPs are organized on a chromosome. Typically, geneticists study the inheritance of genetic variability in extended families in order to determine haplotypes. We do not need to conduct family studies to discover haplotypes. Rather than relying on family studies, we have developed an entirely computerized process for discovering haplotypes. Our proprietary method works because we analyze a large number of individual samples and we have members of extended families in our sample set. We have validated the accuracy of our computerized process by conventional family studies and molecular techniques. We use our proprietary computational methods and algorithms to determine how the SNPs in a gene are organized on each of the two chromosomes in each sample we sequence from our Index Repository. We use the term *HAP*[™] Marker, derived from haplotype, to describe the organization of SNPs we find for a gene.

Our computerized process assigns a confidence value to each *HAP*[™] Marker we discover. If the *HAP*[™] Markers we discover for a gene fall below a defined confidence level, we subdivide the gene into regions. We reexamine each region until we identify *HAP*[™] Markers that meet our acceptance level. We then enter each *HAP*[™] Marker into our proprietary *HAP*[™] Database. We also enter other relevant population information, such as the distribution and frequency of each *HAP*[™] Marker among people from different geographical regions. We also include, in our *HAP*[™] Database, other genomic markers that others have identified and are available in public databases.

As of March 3, 2003, we had processed in excess of 7,000 pharmaceutically relevant genes through our production process and deposited their *HAP*[™] Markers and associated information into our *HAP*[™] Database. All of the nearly 500 current drug targets, with identified genomic structure, have gone through our production process. To date, we have found an average of approximately 18 SNPs per gene. There are generally two possible forms of a SNP that are found at a site of genomic variation. Therefore, these 18 SNPs could theoretically be organized into 2^{18} or 262,144 potential *HAP*[™] Markers.

Using our proprietary algorithms, we found that these SNPs are organized into an average of only approximately 19 *HAP*[™] Markers per gene.

The DecoGen[®] Informatics System

We have constructed a proprietary informatics system, called *DecoGen[®]*, which contains the proprietary database of population information for our Index Repository and our proprietary *HAP*[™] Database of *HAP*[™] Markers. These databases can accommodate information from a variety of populations, including individuals suffering from a specific disease and patients in clinical trials, as well as associated data, such as detailed medical histories, including responses to drugs. The portal to these databases is the *DecoGen[®] Informatics System's* search engine, which we designed with an intuitive, graphical user interface so that drug development clinicians can easily manage their data to find a correlation between *HAP*[™] Markers and a drug response.

Our *DecoGen[®] Informatics System* can use either qualitative or quantitative clinical measurements as a clinical endpoint to search for a correlation with our *HAP*[™] Markers. The informatics system has the ability to exchange information with standard software packages used in the pharmaceutical industry and additional tools are also available within the system to help in the design and operation of clinical trials.

HAP[™] Typing

We use the term *HAP*[™] Typing to describe the process of determining which *HAP*[™] Marker is present for each of the two versions of each gene in a patient's clinical sample. We designed our *HAP*[™] Typing capabilities to support our *HAP*[™] Partnership program partners as well as to provide pharmacogenomics support services to pharmaceutical, biotechnology and diagnostic companies, to government and academic groups and to other entities. The first step in searching for a clinical correlation is to do *HAP*[™] Typing on clinical samples. Our *DecoGen[®] Informatics System* contains a proprietary computational tool that determines the minimal number and combination of variable sites, which we must analyze in order to identify, with high confidence, the two *HAP*[™] Markers that are present for each gene in a clinical sample of DNA. This proprietary tool exploits an established genetic principle. That is, the presence of a given form of genomic variation at one position can be highly predictive of the form of genomic variation present at another site in a gene. This predictability reduces the complexity of the information needed to identify a *HAP*[™] Marker in a genomic sample. We can determine this predictability, however, only if we already know the haplotype or the organization of SNPs in a gene. Our *HAP*[™] Markers contain this needed information.

Our Collaborations

Through December 31, 2002, we have entered into the following licenses and collaborations:

AstraZeneca UK Limited

Effective November 29, 2001, we entered into a three-year agreement with AstraZeneca UK Limited, in which AstraZeneca gained limited access to our *HAP*[™] Technology to investigate associations between our *HAP*[™] Markers and disease susceptibility, in exchange for a specified, onetime payment. We granted AstraZeneca a perpetual exclusive license to use those *HAP*[™] Markers that are shown to have a predictive association with a certain disease, for discovering, developing, manufacturing, marketing and selling of AstraZeneca drugs. We also granted AstraZeneca a perpetual, co-exclusive license, with us, to use the predictive *HAP*[™] Markers for discovering, developing, manufacturing, marketing and selling prognostic products used in connection with the sale or prescription of AstraZeneca drugs. In exchange for these license grants, AstraZeneca granted us

options, which expire in 2011, to obtain licenses under its intellectual property for making, using, marketing and selling prognostic and diagnostic products that detect these predictive *HAP*[™] Markers.

BD (Becton, Dickinson and Company)

Effective December 18, 2002, we entered into a training and license agreement with BD. Under the terms of the agreement, we acquired a non-exclusive, non-transferable license to BD's proprietary BDProbeTec[™] ET platform and Strand Displacement Amplification Technology. The license is fully paid up for our internal research and development activities, which are limited to the United States, is royalty-bearing for selling products and services world-wide for genotyping *HAP*[™] Markers in certain fields of use. BD will provide equipment, certain reagents and training on the development of tests.

Biogen, Inc.

Effective December 21, 2001, we entered into an agreement with Biogen, Inc., in which Biogen gained non-exclusive access to selected *HAP*[™] Markers from our *HAP*[™] Database solely for research and development purposes. We receive payments based upon the *HAP*[™] Markers that Biogen selects.

Effective January 31, 2002, we entered into a second agreement with Biogen, Inc., in which we are applying our *HAP*[™] Technology to a study of the pharmacogenetic basis of variability in response to Amevive[®] (alefacept), a biologic developed for the treatment of adults with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. We granted Biogen an exclusive, fee-bearing license to use our *HAP*[™] Markers, which are shown to be predictive of response to this biologic, to develop diagnostic tests for use in connection with marketing Amevive[®]. We also granted Biogen an exclusive option, for a limited time, to acquire an exclusive license to use particular *HAP*[™] Markers for developing and commercializing other products. Biogen agreed to pay us a non-refundable initial fee, research funding and milestone payments based upon the achievement of predetermined goals, as well as payments for the commercial use of our *HAP*[™] Markers in conjunction with the sale of Amevive[®]. The agreement will automatically terminate after a defined number of years. Biogen received certain early termination rights and either party may terminate the agreement early if the other party breaches the agreement. In December 2002, we amended the agreement to define additional work that we would perform as part of the original research plan and for which Biogen agreed to pay us additional research funding.

Johnson & Johnson Pharmaceutical Research & Development, a division of Janssen Pharmaceutica, N.V.

Effective November 22, 2000, we entered into a collaboration agreement with Janssen Research Foundation, referred to as J&J PRD, under which we granted J&J PRD a non-exclusive license to our *HAP*[™] Technology in exchange for the payment of annual subscription fees and other fees described below. We installed our DecoGen[®] Informatics System at one of their sites. We are collaborating with J&J PRD in research projects to identify *HAP*[™] Markers associated with a patient's response to certain J&J PRD drugs. For each of the first two years of the agreement, we received a minimum fee for providing *HAP*[™] Typing services and we continue to be paid for providing our *HAP*[™] Typing services as part of this collaboration. For the first three research projects, we defined product license fees, milestone and royalty payments for drug and diagnostic products that result from these research projects. The agreement will automatically terminate after three years. Either party may terminate the agreement early if the other party breaches the agreement. In November 2002, we amended the agreement with Johnson & Johnson Pharmaceutical Research & Development, the successor to the Janssen Research Foundation. Under the terms of the amendment, we granted J&J PRD exclusive commercial licenses to use *HAP*[™] Marker associations with certain drugs in exchange for specified fees.

Pharmacia & Upjohn Company

Effective December 12, 2002, we entered into an agreement with Pharmacia & Upjohn Company, in which Pharmacia received a non-exclusive license to selected *HAP*[™] Markers from our *HAP*[™] Database solely for internal research purposes and to specific components of our *DecoGen*[®] Informatics System, one of which is a proprietary algorithm to build haplotypes, and access to our *HAP*[™] Typing services for genotyping their clinical samples from a specific project. We installed the *DecoGen*[®] Informatics System at one of their sites. We receive payments based upon the *HAP*[™] Markers that Pharmacia selects and for genotyping their clinical samples and annual fees for access to our *DecoGen*[®] Informatics System. We expect to complete the genotyping in 2003.

Pfizer, Inc.

Effective August 31, 2001, we entered into a one-year agreement with Pfizer Inc., in which Pfizer gained non-exclusive access to selected data from our *HAP*[™] Database. We receive payments based upon the *HAP*[™] Markers that Pfizer selects. In May 2002 and February 2003, we amended the agreement to extend the terms of the agreement first through February 2003 and now through August 31, 2004, respectively.

Intec Web & Genome Informatics Corporation

Effective February 4, 2002, we entered into a two-year agreement with Intec Web and Genome Informatics Corporation, referred to as Intec W&G, in which we appointed Intec W&G as a non-exclusive, authorized sales representative with responsibility for the Japanese market. We agreed to pay Intec W&G a fixed commission on all payments, excluding royalties, we receive from agreements concluded through Intec W&G with Japanese companies. To date, Intec W&G has not brokered any agreements for us.

Visible Genetics, a part of Bayer HealthCare LLC

Effective November 21, 1996, we granted to Visible Genetics, Inc. a worldwide, exclusive license to our patented technology relating to the coupled amplification and sequencing, or CAS, of DNA for diagnostic use. This technology is not part of our *HAP*[™] Technology. Under the terms of the agreement, Visible Genetics paid us a one-time licensing fee and continues to pay us royalties based on global sales of products using the licensed technology. Visible Genetics incorporated the CAS technology in its TruGene[™] HIV diagnostic kit, which they designed to perform pharmacogenomic analysis of HIV and to customize HIV and AIDS therapy for particular patient sub-groups. The FDA granted market clearance for the TruGene[™] HIV diagnostic kit on September 26, 2001. In March 2000, we amended the agreement to, among other things, reduce the amount of royalties payable under the agreement and expand the field of the license to the research products market. In return for the reduction of royalties and broadening of the field, Visible Genetics paid us an additional one-time fee of \$2 million. The term of the agreement extends until the last of the patents covered by the agreement expires. Either party may terminate the agreement early if the other party breaches the agreement, and we can terminate the agreement early if Visible Genetics fails to make any payments. In October 2002, Leverkusen Bayer through its Bayer Corporation completed the acquisition of Visible Genetics, Inc., which is now part of the Diagnostics Division of Bayer HealthCare LLC, and assumed the obligations and rights of Visible Genetics under this agreement.

Sequenom, Inc.

Effective May 28, 2000, we entered into a three-year collaboration agreement with Sequenom, Inc., under which we committed to use Sequenom's MassARRAY[™] system as our exclusive equipment platform for high-throughput SNP analysis in our *HAP*[™] Typing facility. In return, Sequenom provided

equipment and supplies, as well as ongoing access to information about new technology and products in development by Sequenom. In addition, we had the option to be a test site for these new technologies and products. The agreement required us to purchase a minimum number of MassARRAY™ systems and allowed for predetermined pricing of consumables. The agreement would have automatically terminated after three years. In November 2002, we terminated the collaboration agreement and also received notice from Sequenom that we could use purchased Sequenom products to provide commercial services, as part of our pharmacogenomics support services, to third parties, which are not part of our HAP™ Partnership program, without any additional payment or compensation due to Sequenom for such use.

Through March 11, 2003, we have entered into the following additional licenses and collaborations:

Bayer AG and Bayer HealthCare LLC

Effective January 15, 2003, we entered into a research collaboration and an exclusive license agreement with Bayer AG and with Bayer Healthcare LLC through its Diagnostics Division to develop pharmacogenomic markers of drug safety and efficacy for a defined drug category and for certain disease fields. Under the terms of the agreement, each party has contributed portions of intellectual property derived from its respective programs. We will receive funding to apply our HAP™ Technology to Bayer's clinical samples. Bayer will receive exclusive rights to develop and market diagnostic tests based on the results of the collaboration. We are entitled to receive royalties and rights to perform these diagnostic tests in our CLIA-licensed diagnostic laboratory. There are mutual royalty provisions for any pharmaceutical drugs derived from the collaboration. The collaboration will terminate at the end of defined safety and efficacy studies. The agreement will terminate upon the expiration of all licenses and other granted rights and of the obligation to pay royalties. Either party may terminate the agreement early if the other party breaches the agreement.

Millennium Pharmaceuticals, Inc.

Effective January 7, 2003, we entered into a multi-year agreement with Millennium Pharmaceuticals, Inc., under which we granted Millennium a non-exclusive license to our HAP™ Technology in exchange for the payment of annual subscription fees. Millennium granted us certain rights to support their DNA biomarkers and pharmacogenomic efforts. Millennium has an option to pay specified annual fees to extend the agreement beyond the defined expiration date. Either party may terminate the agreement early if the other party breaches the agreement.

Wayne State University

Effective March 11, 2003, we entered into an agreement with Wayne State University (WSU) to support WSU's research contract with the National Institute of Child Health and Human Development's Perinatology Research Branch (PRB), which is located at the WSU School of Medicine in Detroit, Michigan. Under the agreement, WSU gained access to specific HAP™ Markers and obtained a limited license to use our DecoGen® Informatics System. We will develop assays for the selected HAP™ Markers and provide high-throughput genotyping on clinical samples provided by WSU and the PRB. We receive a license fee and other payments from WSU. Either party may terminate the agreement early if the other party breaches the agreement. We expect to complete the genotyping in 2003.

Intellectual Property

We rely on patents, trade secrets, non-disclosure agreements, copyrights and trademarks to protect our proprietary technologies and information. In addition, our goal is to license to third parties certain components of our intellectual property that is peripheral to our core products and services.

As of March 3, 2003, our patent portfolio included a total of eight issued patents, which we own or for which we are the exclusive licensee. Our issued patents and pending patent applications include those for:

- *HAP*[™] Markers for pharmaceutically important genes;
- correlations between specific *HAP*[™] Markers and response to albuterol and statins;
- components of our *DecoGen*[®] Informatics System, including the process for assembling *HAP*[™] Markers and for determining clinical associations; and
- processes for integrating personalized medicines into the healthcare system.

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, including confidentiality agreements that provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. Agreements with employees provide that all inventions conceived by the individual while employed by us are our exclusive property.

Competition

There is significant competition among entities attempting to use genomic variation data and informatics tools to develop and market new and existing medicines. We expect the intensity of the competition to increase. We face, and will continue to face, competition from pharmaceutical, biotechnology and diagnostic companies, both in the United States and abroad. Several entities are attempting to identify and assemble SNP and haplotype databases for use as a measure of genomic variation. These databases are based on various technologies and approaches, including the sequencing of either cDNA or genomic DNA and a genome-wide approach or a candidate gene approach. In addition, some of these entities are providing or intend to provide informatics tools for integrating the use of SNPs and haplotypes into the drug development process. These entities include, among others, Perlegen Sciences, Celera Genomics Group and the International HapMap Project. In addition, numerous pharmaceutical companies are developing internal capabilities for identifying and utilizing gene variation data. In order to compete successfully against existing and future entities, we must demonstrate the value of our *HAP*[™] Technology and that our informatics technologies and capabilities are superior to those of our competitors. Many of our competitors have greater resources, gene variation discovery capabilities and informatics development capabilities than we do. Therefore, our competitors may succeed in identifying gene variation and applying for patent protection more rapidly than we do.

We expect that our ability to compete will be based on a number of factors, including:

- the ability of our partners to develop and commercialize therapeutic and diagnostic products based upon our *HAP*[™] Technology;
- our ability to attract and retain partners;
- our ability to commercialize our intellectual property;
- our ability to attract and retain qualified personnel;
- our ability to protect against unauthorized use of our *HAP*[™] Technology under various intellectual property laws and contractual obligations; and
- our ability to secure sufficient resources to fund our *HAP*[™] Technology commercialization programs.

Government Regulation

Regulation by governmental entities in the United States and other countries will be a significant factor in the development, manufacturing and marketing of any product that our partners or we develop. Various federal and, in some cases, state statutes and regulations govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of human therapeutic and diagnostic products. The extent to which these regulations may apply to our partners or us will vary depending on the nature of the product. Currently, the FDA does not require companies seeking product approvals to provide data regarding the correlation between therapeutic response and genomic variation.

Virtually all of the pharmaceutical products developed by our partners will require regulatory approval by governmental agencies prior to commercialization. In particular, the FDA and similar health authorities in foreign countries will impose on these products an extensive regulatory review process before they can be marketed. This regulatory process typically involves, among other requirements, preclinical studies, clinical trials, and often post-marketing surveillance of each compound. This process can take many years and requires the expenditure of substantial resources. Delays in obtaining marketing clearance could delay the commercialization of any therapeutic or diagnostic products developed by our partners, impose costly procedures on our partners' activities, diminish any competitive advantages that our partners may attain and lessen our potential royalties. Any products our partners develop may not receive regulatory approval in a timely fashion or at all.

The FDA regulates human therapeutic and diagnostic products in one of three broad categories: drugs, biologics or medical devices. Products developed using our technologies could potentially fall into any of these three categories.

The FDA generally requires the following steps for pre-market approval of a new drug or biologic product:

- preclinical laboratory and animal tests;
- submission to the FDA of an investigational new drug application, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication;
- submission to the FDA of a new drug application, or NDA, if the FDA classifies the product as a new drug, or a biologic license application, or BLA, if the FDA classifies the product as a biologic; and
- FDA review of the NDA or BLA in order to determine, among other things, whether the product is safe and effective for its intended uses.

The FDA classifies medical devices, which include diagnostic products, as class I, class II or class III, depending on the nature of the medical device and the existence in the market of any similar devices. Class I medical devices are subject to general controls, including labeling, premarket notification and good manufacturing practice requirements. Class II medical devices are subject to general and special controls, including performance standards, postmarket surveillance, patient registries and FDA guidelines. Class III medical devices are those which must receive premarket approval, or PMA, by the FDA to ensure their safety and effectiveness, typically including life-sustaining, life-supporting, or implantable devices or new devices which have been found not to be substantially equivalent to currently marketed medical devices. It is impossible to say at this time, which of these categories, will apply to any diagnostic product incorporating our technologies.

Before a new device can be introduced into the U.S. market, it must, in most cases, receive either premarket notification clearance under section 510(k) of the Food, Drug, and Cosmetic Act or approval pursuant to the more costly and time-consuming PMA process. A PMA application must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of clinical trials, bench tests, laboratory and animal studies. A 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed class I or class II medical device or a class III medical device for which the FDA has not called for PMAs. While less expensive and time-consuming than obtaining PMA clearance, securing 510(k) clearance may involve the submission of a substantial volume of data, including clinical data, and may require a lengthy substantive review.

Even if regulatory clearance is obtained, a marketed product and its manufacturer are both subject to continuing review. Discovery of previously unknown problems with a product may result in withdrawal of the product from the market, which could reduce our revenue sources and hurt our financial results. Violations of regulatory requirements at any stage during the process, including preclinical studies and clinical trials, the review process, post-marketing approval or in manufacturing practices or manufacturing requirements, may result in various adverse consequences to us, including:

- the FDA's delay in granting marketing clearance or refusal to grant marketing clearance of a product;
- withdrawal of a product from the market; or
- the imposition of civil or criminal penalties against the manufacturer and holder of the marketing clearance.

Generally, similar regulatory requirements apply to products intended for marketing outside the United States.

We use clinical samples of blood from individuals in developing our intellectual property consisting of *HAP*[™] Markers and *HAP*[™] Marker associations. In some cases, a clinical research organization, or CRO, with which we have a contract, collects these blood samples, plus personal and medical information about each individual. In other cases, we collect DNA plus personal and medical information without the assistance of a CRO. Our CRO prepares, subject to our approval, the sample collection protocol and the patient informed consent form, as well as identifying the clinical sites, which collect the samples. The individual clinical sites recruit the patients for each clinical study and, following the study protocol, explain and obtain the signed and witnessed informed consent documents from each patient. The informed consent form includes the patient's authorization to use the patient's blood sample and data derived from it for developing commercial products. Our contract with the CRO requires an independent institutional review board to approve the study protocol, the patient informed consent form, and the transmission of the samples to us. Either we do not know the identity or we have in place procedures to maintain the confidentiality of any of the individuals from whom we receive clinical samples. We believe that these procedures comply with all applicable federal, state and institutional regulations.

While the FDA does not currently regulate our *HAP*[™] Typing facility, CLIA defines standards that constitute good clinical laboratory practice. Although this is a federal law, each state is responsible for administering the statute. In April 2002, the Connecticut Department of Public Health inspected our laboratory and issued a CLIA license for our *HAP*[™] Typing facility, which can now provide diagnostic test results in support of therapeutic or medical interventions. As a CLIA licensed diagnostic laboratory, inspectors from the Connecticut Department of Public Health can inspect our laboratory at any time to insure that we are in compliance with CLIA.

Research and Development

For the years ended December 31, 2002, 2001 and 2000, we spent approximately \$23.9 million, \$46.3 million and \$27.4 million, respectively, on research and development activities.

Human Resources

As of March 3, 2002, we had 104 full-time employees, 83 of whom were engaged in research and development activities, 8 of whom were engaged in business development and 13 of whom conducted general and administrative functions. Of the 83 employees engaged in research and development activities, 36 were engaged in industrial genomics, 33 were engaged in bioinformatics, software development and information technology, 6 were engaged in medical affairs activities, 5 were engaged in population genomics and 3 were engaged in intellectual property. Thirty-one of our employees hold Ph.D. and/or M.D. degrees and 17 hold other advanced degrees.

None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

ITEM 1A. EXECUTIVE OFFICERS

Set forth below is certain information regarding our current executive officers, including their respective ages as of March 3, 2003:

Name	Age	Position
Kevin Rakin	42	President, Chief Executive Officer and Director
Gualberto Ruaño, M.D., Ph.D.	43	Vice Chairman, Chief Scientific Officer and Director
Gerald F. Vovis, Ph.D.	60	Executive Vice President and Chief Technology Officer
Richard S. Judson, Ph.D.	44	Senior Vice President of Medical Affairs and Informatics
Joseph Keyes	45	Chief Financial Officer and Vice President

Kevin Rakin. Mr. Rakin was appointed Chief Executive Officer, in addition to President, in August 2002. He cofounded Genaissance and has served as a Director since 1995. Mr. Rakin has served as the Company's President since October 2000. From 1995 through 2002, Mr. Rakin also served as Chief Financial Officer and, from January 1997 to October 2000, as our Executive Vice President. Prior to 1998, Mr. Rakin was also a Principal at the Stevenson Group, a consulting firm, where he provided financial and strategic planning services to high-growth technology companies and venture capital firms. Prior to this, Mr. Rakin was a manager with Ernst & Young's entrepreneurial services group. Mr. Rakin holds a B.S. in business and a M.S. in finance from the University of Cape Town and a M.B.A. from Columbia University.

Gualberto Ruaño, M.D., Ph.D. Dr. Ruaño was appointed Vice Chairman and Chief Scientific Officer in August 2002. From 1995 through August 2002, he served as Chief Executive Officer. Dr. Ruaño has served as a Director since 1995. Prior to cofounding Genaissance, he was involved in developing genetic mapping products and services for BIOS Laboratories, Inc. and engaged in research at Yale University, where he focused on haplotyping technologies for profiling genome diversity stemming from population genetics. Dr. Ruaño holds a B.A. in biophysics from The Johns Hopkins University and a M.D. and a Ph.D. in population genetics from Yale University, where he was a fellow of the Medical Scientist Training Program and the Ford Foundation.

Gerald F. Vovis, Ph.D. Dr. Vovis was appointed Executive Vice President, in addition to Chief Technology Officer, in April 2002. He has served as our Chief Technology Officer since October 2000. From October 2000 to April 2002, Dr. Vovis was a Senior Vice President and, from April 1999 to October 2000, was our Senior Vice President of Genomics. From 1980 to 1999, he was affiliated with Genome Therapeutics Corporation, a genomics company, most recently as Senior Vice President of Scientific Affairs. Dr. Vovis has twenty-three years of experience in the management of genetic research

and in the development and management of collaborative research programs with pharmaceutical and biotechnology companies. Dr. Vovis holds a B.A. in chemistry from Knox College and a Ph.D. in biology from Case Western Reserve University.

Richard S. Judson, Ph.D. Dr. Judson has been our Senior Vice President of Medical Affairs and Informatics since August 2002. From April 2000 to August 2002, Dr. Judson was our Senior Vice President of Informatics and, from November 1999 to April 2000, our Vice President of Informatics. He joined Genaisance in February 1999 as Associate Director, Bioinformatics. From January 1997 to February 1999, Dr. Judson served as Group Leader in the Bioinformatics Department of CuraGen Corporation, a genomics company, where he was responsible for developing software for protein-protein interactions and DNA sequence analysis. From January 1990 to December 1996, he served as Senior Member of the Technology Staff at Sandia National Laboratories, leading modeling projects in several areas including computational drug design, protein modeling and sequence analysis. He holds a B.A. in chemistry and physics from Rice University and a M.A. and a Ph.D. in chemistry from Princeton University.

Joseph Keyes. Mr. Keyes was appointed Chief Financial Officer and Vice President in July 2002. Previously, he served as Executive Director of Finance since joining the Company in March 2001. From March 2000 until joining Genaisance, Mr. Keyes served as Vice President of Finance at DSL.net. From June 1999 to February 2000, he served as Vice President, Finance and Chief Financial Officer at Heritage Consumer Products. Previous to that, Mr. Keyes was the Group Controller for United States Surgical Corporation from 1992 to 1999. He holds a B.S. in business administration from Bryant College. Mr. Keyes is a certified public accountant.

ITEM 2. PROPERTIES

Our executive offices and laboratories are located at Five Science Park, New Haven, Connecticut. We lease nearly 72,000 square feet of space, under a lease expiring on September 30, 2006, which we may extend for 10 years. We believe that our current facilities and the space available to us under a lease extension are suitable to meet our current requirements and that suitable additional space will be available on commercially reasonable terms, if required.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to stockholders for a vote during the fourth quarter of 2002.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is currently quoted on the Nasdaq National Market under the symbol "GNSC."

Our common stock began trading on August 1, 2000 and the high and low closing sale prices, as reported on the Nasdaq National Market for the periods indicated, were as follows:

	<u>High</u>	<u>Low</u>
2001		
First Quarter	\$17.50	\$5.50
Second Quarter	\$14.04	\$7.69
Third Quarter	\$12.92	\$3.89
Fourth Quarter	\$ 5.99	\$2.90
	<u>High</u>	<u>Low</u>
2002		
First Quarter	\$ 4.58	\$2.47
Second Quarter	\$ 2.68	\$1.32
Third Quarter	\$ 1.35	\$0.46
Fourth Quarter	\$ 1.40	\$0.40

As of March 14, 2003, there were approximately 279 holders of record of our common stock.

We have never paid cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, for use in our business.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and the results of operations should be read in conjunction with the "Selected Financial Data" and our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. For this purpose, statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects" and similar expressions are intended to identify forward-looking statements. These forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Actual results may differ materially from those indicated in such forward-looking statements as a result of certain factors including, but not limited to, those set forth under the heading "Factors Affecting Future Operating Results".

Overview

Since our inception, we have incurred significant operating losses and, as of December 31, 2002, we had an accumulated deficit of \$193.8 million. The majority of our operating losses have resulted from costs we incurred developing our HAP™ Technology, in our clinical trials and administrative costs associated with operations. We expect to dedicate a significant portion of our resources for the foreseeable future to service our HAP™ Partnership program and STRENGTH program partners, our pharmacogenomics support services customers, our CARING program and to maintain our HAP™ Technology. To date, our revenue has been primarily from licensing and service fees from our agreements with AstraZeneca UK Limited, Biogen, Inc., Gene Logic, Inc., J&J PRD and Pfizer, Inc., as well as a sublicensing agreement with Visible Genetics, Inc. and, to a lesser extent, government grants.

In August 2002, we announced a restructuring and cost reduction program to revise our business focus and to better align our operating cost structure with our current and projected partner needs and projected revenues from our current and projected partners. The cost reduction program included a realignment of management responsibilities, a reduction in our workforce and a decision to seek partners for all internal product development programs. The workforce was reduced by 20 percent to 110 employees in the third fiscal quarter, with the majority of the workforce reductions occurring in the DNA sequencing facility and related informatics support. We incurred a charge for severance and related costs of approximately \$200,000, which was recorded in operating results in the third fiscal quarter of 2002. All severance obligations associated with this workforce reduction had been paid by December 31, 2002.

As a result of the restructuring and cost reduction program, we expect future operating expenses to decrease from prior levels, primarily in research and development expenses. In addition to reducing expenses, our plans and projections reflect a measurable reduction in our negative operating cash flow. These planned reductions in our negative operating cash flow assume significant year over year increases in revenues. There can be no assurance that revenues will continue to increase or that there will continue to be a decrease in the level of cash used to fund operations. If we are not successful in increasing revenues or reducing expenses, as planned, we may not be able to maintain our operations at planned levels.

During the second quarter of 2002, we recorded a \$6.0 million charge for the impairment of fixed assets. This charge relates to sequencing equipment, computer hardware and software and leasehold improvements in our DNA sequencing facility that we determined needed to be reviewed for potential impairment. As a result of our review, we determined that the carrying value of the assets was in excess of discounted future cash flows to be generated by the asset group and we recorded a write-down of

\$6.0 million. We continue to review our fixed assets for potential impairment and, based upon our current cash flow projections, have determined that there has not been an additional impairment of our fixed assets.

In November 2002, we announced that we had amended our collaboration agreement with a customer which accounted for 46% of our revenue for the year ended December 31, 2002. The amendment clarifies the intellectual property rights granted pursuant to the agreement. This agreement expires in the fourth quarter of 2003 unless an extension is negotiated. A collaboration agreement with a customer that accounted for 25% of our revenue for the year ended December 31, 2002, expired in the fourth quarter of 2002.

In December 2002, we announced that we received a notice from General Electric Capital Corporation (GE), claiming that an event of default had occurred under our lease agreement as a result of an alleged material adverse change in our business. We also received a notice from Finova Capital Corporation (Finova), stating that as a result of the default claim by GE, there was a cross-default under our agreement with Finova. Both lessors declared that all principal and future interest obligations were immediately due and payable. In March 2003, we settled the claim with GE and simultaneously amended our lease agreement (GE Amendment). In connection with the GE Amendment, and as additional security for our payment obligations to GE, we delivered to GE a \$2 million irrevocable letter of credit and agreed to additional covenants. It is expected that the letter of credit will be adjusted on a quarterly basis commencing October 1, 2003 based on a decrease in outstanding amounts due to GE, as defined. In connection with the amendment, GE retroactively rescinded their default claim. The GE Amendment and letter of credit has been retroactively reflected in the accompanying 2002 financial statements. We have not entered into a settlement agreement with Finova. Accordingly, we have recorded an additional charge to interest expense to reflect the remaining interest and principal currently due and payable under the Finova capital lease agreement.

We enter into discussions from time to time regarding the acquisition of or strategic investment in other businesses or technologies. We are currently in negotiations with respect to the acquisition of all or substantially all of the assets of a company with technologies we believe are complementary to ours. We cannot assure you if we will be successful in these negotiations.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). Our significant accounting policies are described in Note 1 to the Financial Statements. The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the Financial Statements and accompanying footnotes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from estimates under different conditions, sometimes materially. Critical accounting policies and estimates are defined as those that are both most important to the portrayal of our financial condition and results and require management's most subjective judgments.

Our critical accounting policies are as follows:

- Revenue recognition
- Valuation of long-lived assets
- Research and development expenses

Revenue recognition. We recognize license and service revenue from our agreements with third parties. The revenue includes fees we receive for the license of our HAP™ database and proprietary software, milestone payments based on the achievement of certain goals and services fees for providing specific data on genetic variation. Upfront, non-refundable fees received in connection with a collaboration agreement are deferred and amortized into revenue over the term of the agreement. License revenues are recognized ratably over the access period of the agreement. Revenue derived from the achievement of a milestone is recognized when the milestone is achieved, provided that the milestone is substantive and a culmination of the earnings process has occurred. Service fees are recorded as the services are performed. Revenues derived from the achievement of milestones or recognition of related work when performed under the terms of a contract, as well as the access period of the license agreement, may cause our operating results to vary considerably from period to period.

Valuation of long-lived assets. We assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Factors which could trigger an impairment review, include:

- a significant adverse change in the extent or manner in which a long-lived asset is being used;
- a significant adverse change in the business climate that could affect the value of a long-lived asset; and
- a significant decrease in the market value of assets.

When determining whether the carrying value of the long-lived assets is recoverable we make certain estimates and assumptions regarding the undiscounted cash flows and discounted cash flows expected to be generated by the assets. We determine the discounted future cash flow using a discount rate determined by our management to be commensurate with the risk inherent in our current business. A change in our estimates or the manner in which we use the asset may cause results to vary from period to period.

Research and development expenses. We record research and development expenses when they are incurred or, in the case of clinical trial expenses, based upon information we receive from third party CROs. Research and development expenses include the following major types of costs: salaries and benefits, material and reagent costs, research license fees, clinical trial expenses, depreciation and amortization of lab equipment and leasehold improvements and building and utility costs related to research space. Vendor contractual costs consist primarily of consulting arrangements and certain clinical trial expenses. We expense clinical trial costs as incurred based on information we receive from third parties and estimates that we make. Our estimates may change as additional information becomes available which could cause results to vary from period to period.

Results of Operations

Years Ended December 31, 2002 and 2001

Revenue consists primarily of proceeds received in connection with the licensing of our HAP™ Technology, service revenue and sublicensing of patents. Revenue increased to \$8.1 million in 2002 from \$5.3 million in 2001. The increase in license revenues is attributable to the commercialization of our HAP™ Technology, including agreements entered into with Biogen during 2002, AstraZeneca during 2001 and J&J PRD during 2000. Revenue from Gene Logic, Inc., J&J PRD and Pfizer, Inc. accounted for 82% and 94% of our total revenue in fiscal 2002 and 2001, respectively. Revenue from each of these customers accounted for 10% or more of our total revenue for 2002 and 2001, respectively. Revenue for fiscal 2002 includes a payment received from J&J PRD in the fourth quarter for achieving a milestone. We are recognizing the annual license and subscription fees over the term of the agreements and the service fees as the services are performed. Future milestone and royalty payments, when and if received, will be recognized when earned. Revenue also includes the

amortization, over the remaining life of the sublicensed patent, of upfront payments received in connection with the sublicensing of a patent.

Research and development expenses consist primarily of payroll and benefits for research and development personnel, materials and reagent costs, costs incurred in connection with clinical trials, depreciation and maintenance costs for equipment used for *HAP*[™] Marker discovery and *HAP*[™] Typing, and facility-related costs. We expense our research and development costs as incurred. Research and development costs decreased to \$23.9 million in 2002 from \$46.3 million in 2001. The decrease in research and development expenses in 2002 is primarily attributable to a decrease of approximately \$9 million in expenditures related to our clinical trials, a decrease of approximately \$5 million in material and reagent costs associated with the discovery of new *HAP*[™] Markers, a decrease of approximately \$2 million in payroll and related costs and a decrease of approximately \$1 million in technology license fees. The decrease in clinical trial expenses is primarily due to our STRENGTH Trials, which were substantially completed by December 31, 2001. The decrease in material and reagent costs is primarily due to a reduction in DNA sequencing consistent with the removal of the majority of our ABI Prism[®] 3700 DNA Analyzers from production in the quarter ended June 30, 2002. The decrease in payroll and related costs is primarily due to our work force reduction in connection with our restructuring program. We expect to continue to devote substantial resources to research and development expenses in the near future as we continue to service our *HAP*[™] Partnership program and STRENGTH program partners, our pharmacogenomic support services customers, our CARING program and to maintain our *HAP*[™] Technology. We expect research and development expenses to decrease modestly in 2003 as a result of the restructuring program that we initiated in August 2002.

General and administrative expenses consist primarily of payroll and benefits for executive, business development, finance, public affairs and other administrative personnel, as well as facility related costs and outside professional fees incurred in connection with corporate development, general legal and financial matters. General and administrative expenses decreased to approximately \$8.8 million in 2002 from \$11.9 million in 2001. The decrease in general and administrative expenses in 2002 is primarily due to a \$2 million decrease in consulting and professional service fees and a general reduction in expenses as part of our cost reduction program initiated during 2002.

The \$6.0 million impairment of fixed assets charge relates to sequencing equipment, computer hardware and software and leasehold improvements in our DNA sequencing facility. During the quarter ended June 30, 2002, our management determined that certain conditions had arisen during the quarter that triggered the need for a review of our long-lived assets for potential impairment. These conditions included, but were not limited to, the overall business climate in which we operate and a significant change in the manner in which we were utilizing our DNA sequencing facility and related assets. In particular, during the quarter ended June 30, 2002, we determined that our sequencing production capacity significantly exceeded our forecasted demand for the foreseeable future, which resulted in our decision to remove from production the majority of our ABI Prism[®] 3700 DNA Analyzers, the primary assets of the group. Accordingly, we performed an impairment review on our sequencing long-lived assets. As a result of our review, we determined that the carrying value of the assets was in excess of the projected undiscounted cash flows to be generated by the asset group. To determine the amount of the impairment charge, we compared the carrying value of the applicable fixed assets to their fair value. We determined the fair value of the fixed assets by discounting expected future cash flows using a discount rate determined by our management to be commensurate with the risk inherent in our current business. As a result of our analysis, we determined that the carrying value of the assets was in excess of discounted future cash flows to be generated by the asset group and we recorded a write-down of \$6.0 million. The impairment charge has been allocated to the individual assets on a pro-rata basis. The revised carrying value of the assets is being depreciated over the average remaining life of the primary assets of the group.

Interest income decreased to approximately \$1.0 million in 2002 from \$3.9 million in 2001. The decrease is the result of higher cash, cash equivalent and short-term investment balances in 2001 and the much lower interest rates on investments during 2002.

Interest expense increased to approximately \$3.5 million in 2002 from \$2.6 million in 2001. The increase is primarily due to recording additional interest expense during the quarter ended December 31, 2002, in connection with certain events of default. In December 2002, we received a notice from GE claiming that an event of default had occurred under our lease agreement as a result of an alleged material adverse change in our business. Because of the alleged default, GE declared that all principal and future interest obligations were immediately due and payable. GE also filed a complaint in the Superior Court of the State of Connecticut, demanding payment of all amounts due under the lease agreement. We also received a notice from Finova, stating that as a result of the default claim by GE, there had been a cross-default under our agreement with Finova. Finova declared that all principal and future interest obligations were immediately due and payable. In March 2003, we settled the claim with GE and simultaneously amended our lease agreement (GE Amendment). In connection with the amendment, GE retroactively rescinded their default claim and both parties have withdrawn from any legal action. As we have not entered into a settlement agreement with Finova, we have recorded an additional charge to interest expense to reflect the fact that all future interest and principal is currently due and payable under the Finova capital lease agreement. If, in the future, we enter into a settlement or amend our agreement with Finova it may result in the reversal, in the period of amendment or settlement, of the remaining interest expense recognized in the fourth quarter. The status of the capital lease obligations is discussed further in "Liquidity and Capital Resources".

State income tax expense (benefit) decreased to an expense of \$35,000 in 2002 from a benefit of \$4.1 million in 2001. The benefit represents a net tax benefit from the State of Connecticut as a result of legislation which allowed companies to receive cash refunds from the State at a rate of 65% of their incremental research and development tax credit, as defined, in exchange for foregoing the carryforward of the research and development tax credit. The State of Connecticut rescinded the legislation in 2002.

Years Ended December 31, 2001 and 2000

Revenue consists primarily of proceeds received in connection with the licensing of our *HAP*[™] Technology, service revenue and sublicensing of patents. Revenue increased to \$5.3 million in 2001 from \$753,000 in 2000. The increase in license revenues is attributable to the commercialization of our *HAP*[™] Technology, including an agreement entered into with Pfizer during 2001, as well as agreements entered into with J&J PRD and Gene Logic, Inc. during 2000. Revenue from each of J&J PRD, Gene Logic, Inc. and Pfizer, Inc. accounted for 10% or more of our total revenue in fiscal 2001. J&J PRD, Gene Logic, Inc. and Visible Genetics, Inc. each accounted for 10% or more of our total revenue in 2000. We are recognizing the annual license and subscription fees over the term of the agreements and the service fees as the services are performed. Future milestone and royalty payments, when and if received, will be recognized when earned. Revenue also includes the amortization, over the remaining life of the sublicensed patent, of upfront payments received in connection with the sublicensing of a patent.

Research and development expenses consist primarily of payroll and benefits for research and development personnel, materials and reagent costs, costs incurred in connection with clinical trials, depreciation and maintenance costs for equipment used for *HAP*[™] Marker discovery and *HAP*[™] Typing, and facility-related costs. Research and development costs increased to \$46.0 million in 2001 from \$25.7 million in 2000. Research and development expenses include stock based and other non-cash compensation charges of \$351,000 and \$1.7 million for 2001 and 2000, respectively, for options granted to employees, scientific advisory board members and consultants. The overall increase in research and development expenses in 2001 is primarily attributable to an increase in expenditures

related to our clinical trials, the expansion of our *HAP*[™] Typing process, and the increase in resources dedicated to supporting and improving our proprietary *DecoGen*[®] Informatics System. The increase in expenses includes a \$7.9 million increase in costs related to our clinical trials, a \$2.7 million increase in payroll and related costs, a \$2.3 million increase in technology licenses and a \$4.6 million increase in depreciation expense. The decrease in stock based compensation is primarily due to our decision to vest fully all unvested options previously granted to scientific advisory board members in March 2000, which resulted in a one-time expense of approximately \$1.4 million.

General and administrative expenses consist primarily of salary and related costs for executive, business development, finance, public affairs and other administrative personnel, as well as facility related costs and outside professional fees incurred in connection with corporate development, general legal and financial matters. General and administrative expenses increased to approximately \$11.8 million in 2001 from \$8.8 million in 2000. General and administrative expenses include stock based and other non-cash compensation charges of \$147,000 and \$3.6 million for 2001 and 2000, respectively for options granted to employees, directors and consultants. The increase in general and administrative expenses in 2001 is primarily due to increased salary and related costs as a result of the expansion of our business development activities and the additional costs of operating as a public company for a full fiscal year. The increase in general and administrative expenses is partially offset by a decrease in stock based compensation due to the recording of approximately \$2.9 million of expense during 2000 which related to a stock purchase agreement between two officers and a former executive officer which we recognized as compensatory and accordingly recognized non-cash compensation based on the increase in the fair value of the stock through the date of our initial public offering.

Sublicensing royalty expense represents royalty obligations incurred by us on sublicensing fees that we receive. Sublicensing royalty expense decreased to \$54,000 in 2001 from \$530,000 in 2000. This decrease relates primarily to a nonrefundable cash payment received in 2000 in connection with an amendment to a patent sublicensing agreement. We elected to recognize this expense in 2000 as paid.

Interest income (expense), net decreased to approximately \$1.3 million in 2001 from \$2.8 million in 2000. The decrease is the result of higher cash, cash equivalent and short-term investment balances in 2000 as a result of proceeds received from our sale of Series B and Series C preferred stock in February and March 2000, respectively, and our initial public offering in August 2000. The decrease is also the result of an increase in interest expense as a result of higher capital lease and other debt obligations to fund the acquisition of equipment and partially fund the expansion of our facilities.

State income tax benefit of \$4.1 million represents a net tax benefit from the State of Connecticut as a result of recent legislation which allows companies to receive cash refunds from the State at a rate of 65% of their incremental research and development tax credit, as defined, in exchange for foregoing the carryforward of the research and development tax credit.

Liquidity and Capital Resources

We have financed our operations primarily through the private and public sale of common and preferred stock, government research grants, payments under licensing agreements, loans and capital leases. From inception through December 31, 2002, we have received aggregate gross proceeds of approximately \$163.1 million from issuance of common and preferred stock. In addition, through December 31, 2002, we have received \$4.5 million of government grant funding and \$17.8 million from license and service fees, royalties and research contracts. We also have received \$26.2 million from capital lease financing arrangements and \$8.2 million from other loans. Through December 31, 2002, we have acquired \$41.8 million of property and equipment. These assets were largely financed through capital lease financing arrangements and other loans.

We expect to continue to finance our operations in the short-term from cash we received in 2000 from the sale of our common and preferred stock and revenue from our *HAP*[™] Partnership program

partners and our pharmacogenomics support services customers. Our business strategy depends on, among other things, entering into partnership agreements with pharmaceutical and biotechnology companies. If we are unsuccessful in marketing our partnership programs and pharmacogenomic support services, we may not generate sufficient revenues to sustain our operations at planned levels.

Cash used in operations for the year ended December 31, 2002 was \$18.5 million compared with \$40.1 million for the same period in 2001. The cash used in operations for the year ended December 31, 2002 resulted primarily from a net loss of \$33.1 million and a \$4.9 million decrease in accounts payable and accrued liabilities, partially offset by \$14.2 million of non-cash charges for depreciation and amortization expense and impairment of fixed assets, a \$2.6 million increase in deferred revenue and a \$2.0 million decrease in other current assets including the receipt, in September 2002, of \$1 million from the State of Connecticut for the sale of research and development tax credits.

Cash provided by investing activities was \$18.8 million in 2002 compared with \$2.5 million in 2001. In 2002, we used cash to purchase \$70,000 of property and equipment and received proceeds of \$28.5 million from the liquidation of investments in marketable securities and used cash to purchase \$9.6 million of marketable securities.

Cash used in financing activities was \$9.0 million in 2002 compared to \$6.4 million in 2001. During 2002, we repaid debt of approximately \$6.9 million and were required to provide cash collateral of \$2.1 million in connection with the letter of credit issued as part of the GE Amendment.

Our contractual cash obligations as of December 31, 2002, are as follows:

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Fiscal 2003	Fiscal Years 2004 and 2005	Fiscal Years 2006 and 2007	Fiscal Year 2008 and later
Long-Term Debt, including interest . . .	\$ 6,472	\$ 704	\$1,408	\$1,408	\$2,952
Capital Lease Obligations	11,187	11,187*	—	—	—
Operating Leases	9,230	1,178	2,235	2,025	3,792
Minimum License Obligations	500	88	206	206	—
Total Contractual Cash Obligations . . .	<u>\$27,389</u>	<u>\$13,157</u>	<u>\$3,849</u>	<u>\$3,639</u>	<u>\$6,744</u>

* Reflects all lease obligations as being current. However, as a result of the March 2003 GE Amendment, we anticipate paying the outstanding GE lease obligation under the original maturity schedule through February, 2005.

Long-term debt consists primarily of three financing agreements with Connecticut Innovations, Inc. (CII), a stockholder of the Company, used to finance certain leasehold improvements and other costs associated with our facility expansion. Each agreement provides for interest only for a certain period with principal payments, based on a 120 month amortization, beginning in April 2001 through October 2002, and with final balloon payments due in March 2009 through June 2011. Borrowings under the agreements bear interest at 6.5% and are secured by the related leasehold improvements. The Company was in compliance with all debt covenants as of December 31, 2002 and no cross default provisions exist in the agreements.

Capital lease obligations, related to equipment, consist principally of arrangements with four equipment leasing companies. The leases have terms ranging from two to four years with installments originally scheduled to end between August 2003 and October 2004 and which bear interest at rates ranging from 8.15% to 12.46%. The majority of the capital lease arrangements allow for the purchase of the related equipment at the completion of the lease term, as defined in the agreements, and certain of the agreements require the purchase of the equipment at the completion of the lease term. In

December 2002, the Company announced it received a notice from GE claiming that an event of default had occurred under the lease agreement as a result of an alleged material adverse change in the Company's business. Because of the alleged default, GE declared that all principal and future interest obligations were due and payable immediately. GE also filed a complaint in the Superior Court of the State of Connecticut, demanding payment of all amounts due under the lease agreements. The Company also received a notice from Finova, stating that as a result of the alleged default claim by GE, there was a cross-default under the Company's agreement with Finova. In connection with a cross-default, Finova declared that all principal and future interest obligations were due and payable immediately. In March 2003, the Company and GE agreed to an amendment to their existing lease agreement. In connection with this amendment, GE has rescinded and withdrawn its default claim and both parties have withdrawn from any legal action. The lease amendment requires certain additional covenants as well as a \$2 million letter of credit, which is collateralized by cash. Because of the outstanding claim of default by Finova, the Company recorded an additional charge to interest expense during 2002. This charge represents all future interest payments due under the terms of the agreement with Finova. As of December 31, 2002, the Company has classified as current the GE and Finova lease obligations, as a result of continuing material adverse change provisions within the GE agreement and as a result of the Finova default claim.

We lease our operating facilities located in New Haven, Connecticut. The lease agreements require annual lease payments of \$816,000 per year increasing to \$1.1 million per year over the original term which expires in 2006. We have two five-year renewal options to extend the lease agreements beyond the initial term. We are recording the expense associated with the lease on a straight-line basis over the expected term of the lease. In addition to the operating lease agreements for our current facility, we also have operating leases for various office equipment.

In addition, we periodically enter into agreements with third parties to obtain exclusive or non-exclusive licenses for certain technologies. The terms of certain of these agreements require us to pay future royalty payments and certain milestone payments based on product sales or sublicense income generated from applicable technologies, if any. The amount of such payments will depend upon successful commercialization of applicable technologies, if any. The future minimum payments (assuming non-termination of these leases) are included in the minimum license obligations above.

Capital expenditures are not expected to exceed \$500,000 to \$1 million for each of fiscal 2003 and 2004.

Our cash requirements will vary depending upon a number of factors, many of which are beyond our control, including:

- the demand for our *HAP*[™] Technology;
- the efforts and success of our *HAP*[™] Partnership program;
- the commercialization of intellectual property derived from our associations;
- the level of competition we face;
- our ability to maintain our *HAP*[™] Technology; and
- our ability to manage effectively our operating expenses.

On December 31, 2002, cash, cash equivalents and short-term investments totaled \$34.2 million, which includes \$2.1 million of restricted cash, compared to approximately \$59.7 million at December 31, 2001. Our cash reserves are held in interest-bearing, high-grade corporate bonds and money market accounts. We believe that our existing cash reserves will be sufficient to fund our expected net losses, debt obligations and capital expenditures for at least 12 months. To execute our business plan, we will need to grow our revenues significantly each year and we may need to seek

additional funding through public or private equity offerings, debt financings or commercial partners. We cannot assure you that we will obtain additional partners or capital funding on acceptable terms, if at all.

Income Taxes

We have not generated any taxable income to date and, therefore, have not paid any federal income taxes since inception. On December 31, 2002, we had available unused net operating loss carryforwards of approximately \$121.1 million and \$120.1 million, which may be available to offset future federal and state taxable income, respectively. Use of our federal and state net operating loss carryforwards, which will begin to expire in 2007 and 2003, respectively, may be subject to limitations. The future utilization of these carryforwards may be limited due to changes within our current and future ownership structure as defined within the income tax code. We have recorded a full valuation allowance against our deferred tax asset, which consists primarily of net operating loss carryforwards, because of uncertainty regarding its recoverability, as required by Statement of Financial Accounting Standards No. 109 *Accounting for Income Taxes*.

Recent Accounting Pronouncements

In June 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure, an amendment of FASB Statement No. 123*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value-based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. SFAS No. 148 is effective for fiscal years ending after December 15, 2002 for annual statements and for interim periods ending after December 15, 2002 for interim financial reports. The Company has adopted the disclosure requirements of SFAS No. 148 in its financial statements for the year ended December 31, 2002, but has not determined whether or not it will voluntarily adopt SFAS No. 123 and the related transition alternatives pursuant to SFAS No. 148.

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146 (SFAS No. 146), *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146). This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. We believe the adoption of this new standard will not have a material impact on either our operating results or financial position.

In November 2002 the FASB issued FASB Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (an Interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34)*. FIN 45 clarifies the requirements of FASB Statement No. 5 (FAS 5) *Accounting for Contingencies*, relating to a guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. FIN 45 requires that upon issuance of a guarantee, the guarantor must recognize a liability for the fair value of the obligation it assumes under that guarantee. The initial recognition and measurement provisions are effective for guarantees issued or modified after December 31, 2002. The disclosure requirements under FIN 45 are effective for the Company's fiscal 2002 year-end.

In November 2002, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. This issue addresses revenue recognition for arrangements with multiple deliverables which should be considered as separate units of accounting if the deliverables meet certain criteria as described in EITF 00-21. This issue is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Early application is permitted.

Factors Affecting Future Operating Results

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. These statements are subject to risks and uncertainties and are based on the beliefs and assumptions of our management based on information currently available to our management. Use of words, such as "believes," "expects," "anticipates," "intends," "plans," "estimates," "should," "likely" or similar expressions, indicate a forward-looking statement. Forward-looking statements involve risks, uncertainties and assumptions. Certain of the information contained in this Annual Report on Form 10-K consists of forward-looking statements. Important factors that could cause actual results to differ materially from the forward-looking statements include the following:

We are an early stage company with a history of losses and we expect to incur net losses for the foreseeable future such that we may never be profitable.

We have incurred substantial operating losses since our inception. As of December 31, 2002, we have generated only minimal revenue from our HAP™ Partnership program and our pharmacogenomics support services, and we do not expect to generate significant revenues for several years, if ever. From inception through December 31, 2002, we had an accumulated deficit of approximately \$193.6 million. Our losses to date have resulted principally from costs we incurred in the development of our HAP™ Technology, in our clinical trials and from general and administrative costs associated with operations. We expect to devote our resources to service our HAP™ Partnership program and STRENGTH program partners, our pharmacogenomics support services customers, our CARING program and to maintain our HAP™ Technology.

We expect to incur additional losses this year and in future years, and we may never achieve profitability. In addition, pharmaceutical and biotechnology companies are only now beginning to use products such as ours in their drug and diagnostic development or marketing efforts and, accordingly, they may not choose to use our HAP™ Technology. We do not expect our losses to be substantially mitigated by revenues from our HAP™ Partnership and STRENGTH programs and our CARING program, if any, or from our pharmacogenomics support services for a number of years, if ever.

We currently rely on a limited number of licensing and service arrangements for substantially all of our revenues. As a result, the loss of one major customer or our inability to secure additional significant customers during a given period would have an adverse affect on our business and operating results.

We are dependent upon a limited number of licensing and service arrangements that represent substantially all of our revenues. In the year ended December 31, 2002, three of our customers accounted for 82% of our total revenues. The agreement with the first customer expired by its terms in the fourth quarter of 2002. The agreements with the second and third customers terminate by their terms in the third quarter of 2004 and the fourth quarter of 2003, respectively. If we are unable to replace, upon substantially similar terms, the agreement that expired in 2002 or if we lose either of the remaining significant customers, it would have a material adverse affect on our revenues and on our business in general and could cause volatility or a decline in our stock price.

To generate significant revenues, we must obtain additional customers for our *HAP*[™] Partnership program and our STRENGTH and CARING programs.

Our strategy depends on entering into agreements with pharmaceutical and biotechnology companies for our *HAP*[™] Partnership program and our STRENGTH and CARING programs. We currently have a *HAP*[™] Partnership program with six pharmaceutical and biotechnology companies as well as an agreement with a major diagnostic company to commercialize exclusively the diagnostic rights and non-exclusively the product development rights from our STRENGTH program. We may not obtain additional partners for our *HAP*[™] Partnership program and our STRENGTH program or obtain any partners for our CARING program. If we are unsuccessful in finding additional partners for our *HAP*[™] Partnership program and our STRENGTH program or in finding any partners for our CARING program, we may never generate sufficient revenues to sustain our operations. In addition, we expect that some of our future *HAP*[™] Partnership program collaborations, like some of our current *HAP*[™] Partnership program collaborations, will be limited to specific, limited-term projects or that some of these collaborations may not be renewed. Accordingly, we must continually obtain new customers to be successful. To date, the integration of pharmacogenomics into drug development and marketing has not achieved widespread market acceptance.

If the estimates we make, and the assumptions on which we rely, in preparing our financial statements prove inaccurate, our actual results may vary from these reflected in our projections and accruals.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There can be no assurance, however, that our estimates or the assumptions underlying our estimates will be correct.

We may require additional funding to fund operations and repay debt and we may not be able to obtain any.

We have used substantial amounts of cash to fund our research and development activities. We will continue to spend funds to service our *HAP*[™] Partnership program and STRENGTH program partners, our pharmacogenomics support services customers, our CARING program and to maintain our *HAP*[™] Technology. We plan to pay for these activities with funds from:

- our existing cash and investment securities and
- income that we may receive from our *HAP*[™] Partnership program and STRENGTH program partners and pharmacogenomics support services customers.

We intend to rely on our current *HAP*[™] Partnership program and STRENGTH program partners and future partners, if any, and our current pharmacogenomics support services customers and future customers, if any, for significant funding in the future to support our development efforts. To execute our business plans, we will need to grow our revenues significantly each year. We cannot be certain when we will begin to receive additional income, if at all, from our *HAP*[™] Partnership and STRENGTH programs and our pharmacogenomics support services and income, if any, from our CARING program. If we do not receive this income or do not receive it as rapidly as we expect, we would spend our existing cash and investment securities more rapidly than we currently plan.

We believe that our existing cash reserves will be sufficient to support our expected net losses, debt obligations and capital expenditures for at least 12 months. We cannot assure you that we will be able to obtain new partners or to generate the increased revenues required to meet our business plan

objectives. In addition, to execute our business plans, we may need to seek additional funding through public or private equity offerings, debt financings or commercial partners. We cannot assure you that we will obtain additional partners or capital funding on acceptable terms, if at all. If we are unable to generate sufficient revenues or access capital on acceptable terms, we may be required to (a) obtain funds on unfavorable terms that may require us to relinquish rights to certain of our technologies or that would significantly dilute our stockholders and/or (b) significantly scale back current operations. Either of these two possibilities would have a material adverse effect on our business.

Our *HAP*[™] Technology may not allow our partners to develop commercial products or to increase sales of their marketed products.

We developed our *HAP*[™] Technology on the assumption that information about gene variation and gene variation associated with drug response may help drug development professionals better understand the drug response of particular populations and complex disease processes. Although the pharmaceutical and biotechnology industries are increasing their use of genomics in analyzing drug response and diseases, we are unaware of any successful drug development program applying population genomics.

We discover *HAP*[™] Markers for pharmaceutically relevant genes. If we are unable to find *HAP*[™] Markers for pharmaceutically relevant genes in a timely manner, our potential partners may lose confidence in our *HAP*[™] Technology and our company, and this loss in confidence could decrease our ability to generate revenues. Even if we are able to discover the *HAP*[™] Markers for pharmaceutically relevant genes, this information may not prove to be superior to genomic variation information discovered by our competitors. Furthermore, pharmaceutical and biotechnology companies may not choose our *HAP*[™] Technology over competing technologies.

Our *DecoGen*[®] Informatics System may also be less effective than we expect or may not allow our partners or us to determine a correlation between drug response and genomic variation. Furthermore, even if our partners or we are successful in identifying a specific correlation between drug response and genomic variation based on our *HAP*[™] Technology, our partners may not be able to develop or sell commercially viable products nor may our partners be able to increase the sales of their marketed products using this correlation. Accordingly, our *HAP*[™] Markers and *HAP*[™] Technology may not improve the development, marketing and prescribing of drugs or the development and marketing of diagnostics developed by our *HAP*[™] Partnership program and STRENGTH program partners.

If we are unable to obtain intellectual property protection for our *HAP*[™] Technology, trade secrets or know how, we may not be able to operate our business profitably.

Our success depends, in part, on our ability to protect our *HAP*[™] Technology, any associations that we find between clinical outcomes and genetic variation and any other proprietary software, methods and technologies that we develop, either as a trade secret or under the patent and other intellectual property laws of the United States and other countries, so that we can prevent unauthorized entities from using our inventions and proprietary information. Because patent applications that were filed prior to November 29, 2000 in the United States are confidential until patents issue, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over any patent applications of others. We are aware that there are other firms or individuals who have discovered, or are currently discovering, information similar to the information we are discovering, who may have filed, and in the future are likely to file, patent applications that are similar or identical to our patent applications.

Our pending patent applications may not result in issued patents. The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain as a result of the

uncertain state of the patent law in the biotechnology field. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in biotechnology patents, particularly those involving genomics. In addition, some interest groups are lobbying for restrictions on patenting of genetic tests.

If we cannot establish additional collaborative relationships, we may be unable to develop or commercialize our *HAP*[™] Technology and we will depend on our partners to develop or to co-develop products.

We currently have a *HAP*[™] Partnership program with six pharmaceutical and biotechnology companies as well as an agreement with a major diagnostic company to commercialize exclusively the diagnostic rights and non-exclusively the product development rights from our STRENGTH program. We do not currently have any partners for our CARING program. Under our current strategy, and for the foreseeable future, we do not expect to develop or market pharmaceutical or diagnostic products on our own. As a result, our current and future revenues, in part, will depend on payments from our current *HAP*[™] Partnership program and STRENGTH program partners and our future *HAP*[™] Partnership, STRENGTH and CARING program partners, if any, for either the new products they may develop, or for increased sales of their existing products, made possible through the use of our *HAP*[™] Technology. If we are unable to attract new *HAP*[™] Partnership program and STRENGTH program partners or any partners for our CARING program, we may never generate sufficient revenues to sustain our operations.

Our partners for our *HAP*[™] Partnership program and STRENGTH program and our partners, if any, for our CARING program, will be responsible for pre-clinical study and clinical development of therapeutic and diagnostic products and for regulatory approval, manufacturing and marketing of any products or enhanced marketing claims that result from the application of our *HAP*[™] Technology. Our current agreements and we anticipate that our future agreements with partners for our *HAP*[™] Partnership and STRENGTH programs and with partners, if any, for our CARING program will allow them significant discretion in pursuing these activities. We cannot control the amount and timing of resources that any such current or potential partners will devote to our programs or potential products. Our *HAP*[™] Partnership program and STRENGTH program arrangements and our CARING program arrangements, if any, may also have the effect of limiting the areas of research that we may pursue either alone or with others. Because part of our revenues will be dependent on the successful commercialization or development of our partners' products, if, for any reason, a *HAP*[™] Partnership program partner or our STRENGTH program partner delays or abandons its development or commercialization of a product developed using our *HAP*[™] Technology, we may receive reduced royalty or other payments or no royalty or other payments at all. In addition, because part of our future revenues will be dependent on the successful commercialization of additional aspects of our *HAP*[™] Partnership and STRENGTH programs with partners and the successful commercialization of our CARING program with partners, if, for any reason, a partner delays or abandons its development or commercialization of these additional aspects of our *HAP*[™] Partnership program or STRENGTH program or its development or commercialization of our CARING program, we may receive reduced royalty or other payments or no royalty or other payments at all.

Although we intend to retain the rights to all *HAP*[™] Markers, which we discover as well as to *HAP*[™] Markers discovered jointly with our *HAP*[™] Partnership and STRENGTH program partners and with our CARING program partners, if any, we may not always be able to negotiate the retention of these rights. Furthermore, disputes may arise in the future over the ownership of rights to *HAP*[™] Markers as well as any other technology we develop with our *HAP*[™] Partnership and STRENGTH program partners or with our CARING program partners, if any. These and other possible disagreements between our *HAP*[™] Partnership and STRENGTH program partners and us or between our CARING program partners, if any, and us could lead to delays in the research, development or

commercialization of their products. These disagreements could also result in litigation or require arbitration to resolve. Any of these events could prevent us from effectively marketing our *HAP*[™] Technology.

We invest considerable amounts of time, effort, and money to license our *HAP*[™] Technology; and if we are unable to license our technology, we may not generate sufficient revenue to sustain our operations.

Our ability to obtain partners for our *HAP*[™] Partnership, STRENGTH and CARING programs will depend in significant part upon the pharmaceutical and biotechnology industries' acceptance that our *HAP*[™] Technology can help accelerate or improve their drug and diagnostic development and marketing efforts. To achieve market acceptance, we must continue to educate the pharmaceutical and biotechnology industries and the public in general as to the potential benefits of our *HAP*[™] Partnership, STRENGTH and CARING programs. Most importantly, we must convince the research and development, clinical and marketing departments of pharmaceutical and biotechnology companies that our *HAP*[™] Technology can accelerate and improve the processes for developing, marketing and prescribing drugs and for developing and marketing diagnostics and that our *HAP*[™] Partnership, STRENGTH and CARING programs will be commercially viable. If we fail to gain this acceptance, we may never generate sufficient revenues to sustain our operations. We may expend substantial funds and management effort to market our *HAP*[™] Partnership, STRENGTH and CARING programs, without any resulting revenues.

Our ability to make any acquisitions is dependent on the availability of adequate cash and the attractiveness of our stock price.

We anticipate that any future acquisitions of businesses or technologies will be financed through cash from operations, the issuance of shares of our common stock and/or seller financing. We cannot assure you that we will have sufficient existing capital resources or that we will be able to raise sufficient additional capital resources on terms satisfactory to us, if at all, in order to meet our capital requirements for such acquisitions.

We also believe that a significant factor in our ability to close acquisitions will be the attractiveness of our common stock for potential acquisition candidates. This attractiveness may, in large part, be dependent upon the relative market price and capital appreciation prospects of our common stock compared to the equity securities of our competitors. The trading price of our common stock on the Nasdaq National Market has affected and, could in the future materially adversely affect, our acquisition program.

Integration of acquisitions or strategic investments could interrupt our business and our financial condition could be harmed.

From time to time, we may acquire or make strategic investments in other businesses or technologies. Any acquisitions or strategic investments we may make in the future may entail numerous risks that include the following:

- difficulties integrating acquired operations, personnel, technologies or products, if any;
- diversion of management's focus from our core business concerns;
- entering markets in which we have no or limited prior experience or knowledge;
- exposure to litigation from stockholders or creditors of, or other parties affiliated with, the target company or companies;
- dilution to existing stockholders and earnings per share; and
- incurrence of substantial debt.

Any such difficulties encountered as a result of any mergers, acquisitions or strategic investments could adversely affect our business, operating results and financial condition.

If we are unable to prevent others from unauthorized use of, or are unable to defend our use of, our *HAP*[™] Technology, trade secrets or know how, we may not be able to operate our business profitably.

Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The mere issuance of a patent does not guarantee that it is valid or enforceable; thus, even if we obtain patents, they may not be valid or enforceable against third parties.

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, including confidentiality agreements signed by our employees, academic collaborators and consultants that provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship will be kept confidential except in specified circumstances. Agreements with employees, consultants and collaborators generally provide that all inventions conceived by the individual while employed by us are our exclusive property. If employees, consultants or collaborators do not honor these agreements, we may not have adequate remedies for breach. Furthermore, our trade secrets may otherwise become known or be independently discovered by competitors.

Further, a patent does not provide the patent holder with freedom to operate in a way that infringes the patent rights of others. A third party may sue us for infringing on its patent rights. Likewise, we may need to resort to litigation to enforce a patent issued to us or to determine the scope and validity of third party proprietary rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any party should successfully claim that the creation or use of our *HAP*[™] Technology or *HAP*[™] Marker association data infringe upon their intellectual property rights, in addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license on unfavorable terms. Moreover, any legal action against us or our *HAP*[™] Partnership and STRENGTH program partners or any CARING program partners claiming damages or seeking to enjoin commercial activities relating to the affected products and processes could, in addition to subjecting us to potential liability for damages, require us or our *HAP*[™] Partnership and STRENGTH program partners or any CARING program partners to obtain a license in order to continue to manufacture or market the affected products and processes. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive, and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around a patent, we may be unable to market effectively some of our *HAP*[™] Technology, which could limit our profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Regulatory oversight of our *HAP*[™] Technology and public opinion regarding ethical issues surrounding the use of genetic information may adversely affect our ability to market our *HAP*[™] Technology.

Currently, there is limited FDA regulation of genetic tests. The Secretary's Advisory Committee on Genetic Testing, an advisory panel to the Secretary of the U.S. Department of Health and Human Services, has recommended that the FDA expand its regulation of genetic testing to require FDA

approval for all new genetic tests and labeling of genetic tests. If the FDA adopts this recommendation, it may require that we, or our partners, apply for FDA approval as a prerequisite to marketing genetic tests that incorporate our *HAP*[™] Technology. If the FDA were to deny any application of this kind, it could adversely affect our business and we may be unable to generate sufficient revenues to sustain our operations.

To date, the FDA has not required, in connection with approving any drug, that a physician must have genomic variation information determined about a patient before the doctor prescribes a drug. However, the FDA, in one instance, has required that a physician must have gene expression information about a patient before the doctor prescribes the drug. On January 31, 2003, the FDA announced an initiative to help make innovative medical technology available sooner, including the use of pharmacogenomics during drug development. The FDA indicated that within six months the agency would issue guidance on when and how to submit pharmacogenomic information to the FDA during the drug development process. The FDA said that this guidance would facilitate the exploratory use of pharmacogenomic screening during drug development and would clarify when such information would be considered part of the evaluation of drug safety. In addition, the FDA stated that the agency would hold a workshop in 2003 on issues that are involved in the co-development of a pharmacogenomic test and a drug and that within 18 months the agency would issue guidance on the regulatory pathway for such combinations through the agency's Center for Drug Evaluation and Research and the Center for Devices and Radiological Health. Our success will depend in part on what guidance the FDA issues with regard to the use of genomic variation analysis as part of the drug approval process and, more specifically, the validity of our *HAP*[™] Technology as a basis for identifying genomic variation and for correlating drug response with genomic variation. Without this acceptance by the FDA and the pharmaceutical and biotechnology industry, we may be unable to market effectively our *HAP*[™] Technology and we may not generate sufficient revenues to sustain our operations.

Within the field of personalized health and medicine, governmental and other entities may enact patient privacy and healthcare laws and regulations that may limit the use of genomic variation data. To the extent that these laws and regulations limit the use of our *HAP*[™] Technology or impose additional costs on our partners, we may be unable to market effectively our *HAP*[™] Partnership, STRENGTH and CARING programs and we may not generate sufficient revenues to sustain our operations.

Additionally, public opinion on ethical issues related to the confidentiality and appropriate use of genetic testing results may influence governmental authorities to call for limits on, or regulation of the use of, genetic testing. In addition, governmental authorities or other entities may call for limits on, or regulation of the use of, genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. The occurrence of any of these events could reduce the potential markets for our *HAP*[™] Technology, which could prevent us from generating sufficient revenues to sustain our operations.

Furthermore, we may be directly subject to regulations as a provider of diagnostic information. To the extent that these regulations restrict the sale of our *HAP*[™] Technology or impose other costs, we may be unable to provide our *HAP*[™] Technology to our customers on terms sufficient to recover our expenses.

If our partners do not seek, or do not receive, marketing approval for products developed, if any, using our *HAP*[™] Technology, we may receive delayed royalty or other payments or no royalty or other payments at all.

Any new drug, biologic, or new drug or biologic indication our partners develop using our *HAP*[™] Technology must undergo an extensive regulatory review process in the United States and other countries before a new product or indication of this kind could be marketed. This regulatory process can take many years and require substantial expense. Changes in FDA policies and the policies of

similar foreign regulatory bodies can prolong the regulatory review of each new drug or biologic license application or prevent approval of the application. We expect similar delays and risks in the regulatory review process for any diagnostic product, whenever this regulatory review is required. Even if a product obtains marketing clearance, a marketed product and its manufacturer are subject to continuing review. A manufacturer may be forced to withdraw a product from the market if a previously unknown problem with a product becomes apparent. Because our future revenues will be largely dependent on the successful commercialization or development of products using our *HAP*[™] Technology, any delay in obtaining, failing to obtain, or failing to maintain regulatory approval for a product developed using our *HAP*[™] Technology may delay our receipt of royalty or other payments or prevent us from receiving royalty or other payments sufficient to recover our expenses.

If our partners are unable to obtain FDA approval for therapeutic or diagnostic products developed using our *HAP*[™] Technology, the lack of regulatory approval will diminish the value of our *HAP*[™] Technology.

To date, no one has developed or commercialized any therapeutic product or commercialized any diagnostic product using our *HAP*[™] Technology. We expect to rely on our partners for our *HAP*[™] Partnership and STRENGTH programs and our partners, if any, for our CARING program to file applications for regulatory approval and generally direct the regulatory review process and obtain FDA acceptance of our *HAP*[™] Partnership and STRENGTH programs and our CARING programs, if any. Our partners for our *HAP*[™] Partnership and STRENGTH programs or our partners, if any, for our CARING program, may not submit an application for regulatory review. Even if they do submit applications, they may not be able to obtain marketing clearance for any products on a timely basis, if at all. If our partners fail to obtain required governmental clearances for therapeutic or diagnostic products, they will not be able to market these products unless and until they obtain these clearances. As a result, we may not receive royalty or other payments from our customers. The occurrence of any of these events may prevent us from generating revenues sufficient to sustain our operations.

If we do not successfully distinguish and commercialize our *HAP*[™] Technology, we may be unable to compete successfully with our competitors or to generate revenue significant to sustain our operations.

Numerous entities are attempting to identify genomic variation predictive of specific diseases and drug response and to develop products and services based on these discoveries. We face competition in these areas from pharmaceutical, biotechnology and diagnostic companies, academic and research institutions and government or other publicly-funded agencies, both in the United States and abroad, most of which have substantially greater capital resources, research and development staffs, facilities, manufacturing and marketing experience, distribution channels and human resources than we do.

These competitors may discover, characterize or develop important technologies applying population genomics before us or our partners for our *HAP*[™] Partnership and STRENGTH programs that are more effective than those technologies which we develop or which our partners for our *HAP*[™] Partnership and STRENGTH programs develop, or these competitors may obtain regulatory approvals of their drugs and diagnostics more rapidly than our partners for our *HAP*[™] Partnership and STRENGTH programs do, any of which could limit our ability to market effectively our *HAP*[™] Technology.

Some companies and governments are marketing or developing a number of databases and informatics tools to assist participants in the healthcare industry and academic researchers in the management and analysis of genomic data. Entities such as Perlegen Sciences, Celera Genomics Group and the International HapMap Project have developed or plan to develop databases containing gene sequence, genomic variation or other genomic information and are marketing or plan to market their data to pharmaceutical and biotechnology companies or plan to make freely available their databases. In addition, numerous pharmaceutical and biotechnology companies, such as GlaxoSmithKline plc,

either alone or in partnership with our competitors, are developing genomic research programs that involve the use of information that can be found in these databases.

In order to compete against existing and future technologies, we will need to demonstrate to potential *HAP*[™] Partnership, STRENGTH and CARING program partners the value of our *HAP*[™] Technology and that our *HAP*[™] Technology and capabilities are superior to competing technologies. Although we believe that our focus on gene-based *HAP*[™] Markers, rather than random genomic SNPs or genome-wide haplotypes, differentiates our *HAP*[™] Technology from other technologies that our competitors are developing, any *HAP*[™] Technology improvements we create may fail to achieve greater market acceptance than the technologies developed by our competitors.

Genomic technologies have undergone, and are expected to continue to undergo, rapid and significant change. Our future success will depend in large part on maintaining a competitive position in the genomics field. Others may rapidly develop new technologies that may result in our products or technologies becoming obsolete before we recover the expenses that we incur in connection with the development of these products. Our *HAP*[™] Technology could become obsolete if our competitors offer less expensive or more effective drug discovery and development technologies, including technologies that may be unrelated to genomics.

If we fail to maintain our computer hardware, software and related infrastructure, we could experience loss of, or delay in, revenues and market acceptance.

Because our business requires manipulating and analyzing large amounts of data, we depend on the continuous, effective, reliable and secure operation of our computer hardware, software and related infrastructure. To the extent that our hardware or software malfunctions, we will experience reduced productivity. We protect our computer hardware through physical and software safeguards. However, our computer hardware is still vulnerable to fire, weather, earthquake, or other natural disaster and power loss, telecommunications failures, physical or software break-ins and similar events. In addition, the software and algorithmic components of our *DecoGen*[®] Informatics System are complex and sophisticated, and as such, could contain data, design or software errors that could be difficult to detect and correct. Users of our system may find software defects in current or future products. If we fail to maintain the necessary computer capacity and data to support our computational needs and our customers' drug and diagnostic discovery and development efforts, we could experience a loss in revenues, or a delay in receiving revenues and a delay in obtaining market acceptance for our technology.

Our operating results may fluctuate significantly and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in our common stock price.

Our operating results have fluctuated in the past and we expect they will fluctuate in the future. These fluctuations could cause our common stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- recognition of non-recurring revenues due to receipt of license fees, achievement of milestones, completion of contracts or other revenues;
- demand for and market acceptance of our *HAP*[™] Partnership, STRENGTH and CARING programs;
- timing of the execution of agreements on our *HAP*[™] Partnership, STRENGTH and CARING programs and other material contracts;
- our competitors' announcements or introduction of new products, services or technological innovations;

- disputes regarding patents or other intellectual property rights;
- securities class actions or other litigation;
- adverse changes in the level of economic activity in the United States and other major regions in which we do business; and
- general and industry-specific economic conditions, which may affect our partners' use of our *HAP™* Technology.

Due to volatile and unpredictable revenues and operating expenses, we believe that period-to-period comparisons of our results of operations may not be a good indication of our future performance. It is possible that, in some future periods, our operating results may be below the expectations of securities analysts or investors. In this event, the market price of our common stock could fluctuate significantly or decline.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is principally confined to our cash equivalents and investments, all of which have maturities of less than 12 months. We maintain a non-trading investment portfolio of investment grade, liquid debt securities that limit the amount of credit exposure to any one issue, issuer or type of instrument. The weighted average interest rate on marketable securities at December 31, 2002, was approximately 2.06%. In view of the nature and mix of our total portfolio, a 10% movement in market interest rates would not have a significant impact on the total value of our investment portfolio as of December 31, 2002.

On December 31, 2002, we had aggregate fixed rate debt of approximately \$16.1 million, including borrowings outstanding under term loans and capital lease obligations. The weighted average interest rate on this debt at December 31, 2002, was approximately 9.74%. A 10% change in this interest rate would cause a corresponding increase in our annual expense of approximately \$157,000.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Public Accountants

To the Board of Directors and Stockholders of Genaissance Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheet as of December 31, 2002 and the related statements of operations, of stockholders' equity and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Genaissance Pharmaceuticals, Inc. at December 31, 2002, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on the financial statements based on our audit. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statements presentation. We believe that our audit provides a reasonable basis for our opinion. The financial statements of the Company as of December 31, 2001, and for each of the two years in the period ended December 31, 2001, were audited by other independent accountants who have ceased operations. Those independent accountants expressed an unqualified opinion on those financial statements in their report dated January 25, 2002.

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut

February 1, 2003, except for the item noted
in Footnote 8 for which the date is
March 12, 2003

THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP. THE COMPANY IS UNABLE TO OBTAIN A REISSUE REPORT OR CONSENT TO INCORPORATION BY REFERENCE OF ARTHUR ANDERSEN LLP'S REPORT FROM ARTHUR ANDERSEN LLP BECAUSE ARTHUR ANDERSEN LLP HAS CEASED OPERATIONS.

Report of Independent Public Accountants

To the Board of Directors and Stockholders of Genaissance Pharmaceuticals, Inc.:

We have audited the accompanying balance sheets of Genaissance Pharmaceuticals, Inc. (a Delaware corporation) as of December 31, 2001 and 2000, and the related statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2001. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Genaissance Pharmaceuticals, Inc. as of December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Hartford, Connecticut
January 25, 2002

GENAISSANCE PHARMACEUTICALS, INC.

Balance Sheets

(Amounts in thousands, except per share data)

	December 31,	
	2002	2001
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 16,578	\$ 25,204
Restricted cash	2,100	—
Marketable securities	15,472	34,469
Accounts receivable	448	359
State income tax receivable	—	1,500
Other current assets	407	1,391
Total current assets	35,005	62,923
PROPERTY AND EQUIPMENT, net	14,554	28,508
DEFERRED FINANCING COSTS, net of accumulated amortization of \$586 and \$433 at December 31, 2002 and 2001, respectively	220	374
OTHER ASSETS	943	472
Total assets	\$ 50,722	\$ 92,277
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt, including amounts due to related parties of \$397 and \$187 at December 31, 2002 and 2001, respectively	\$ 397	\$ 672
Current portion of capital lease obligations	11,187	6,759
Accounts payable	838	2,607
Accrued expenses	2,037	4,899
Accrued dividends	1,159	—
Current portion of deferred revenue	3,026	211
Total current liabilities	18,644	15,148
LONG-TERM LIABILITIES:		
Long-term debt due to related party, less current portion	4,501	4,929
Capital lease obligations, less current portion	—	9,834
Deferred revenue, less current portion	1,722	1,928
Accrued dividends	—	1,159
Other	—	300
Total long-term liabilities	6,223	18,150
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock, 58,000 authorized shares at December 31, 2002 and 2001; \$.001 par value; 22,847, and 22,783 shares issued and outstanding at December 31, 2002 and 2001	23	23
Preferred stock, 1,000 authorized shares at December 31, 2002 and 2001; no shares issued or outstanding	—	—
Additional paid-in capital	219,413	219,348
Accumulated deficit	(193,602)	(160,509)
Accumulated other comprehensive income	21	117
Total stockholders' equity	25,855	58,979
Total liabilities and stockholders' equity	\$ 50,722	\$ 92,277

The accompanying notes are an integral part of these financial statements.

GENAISSANCE PHARMACEUTICALS, INC.

Statements of Operations

(Amounts in thousands, except per share data)

	Year Ended December 31,		
	2002	2001	2000
REVENUES:			
License and service revenue	\$ 8,111	\$ 5,345	\$ 678
Grant revenue	—	—	75
	8,111	5,345	753
OPERATING EXPENSES:			
Research and development	23,940	46,333	27,374
General and administrative	8,799	11,933	12,399
Impairment of fixed assets	6,000	—	—
Sublicense royalty fees	—	54	530
	38,739	58,320	40,303
Operating loss	(30,628)	(52,975)	(39,550)
OTHER INCOME (EXPENSE):			
Interest expense	(3,467)	(2,599)	(1,839)
Interest income	1,037	3,918	4,623
Loss before income taxes	(33,058)	(51,656)	(36,766)
State income tax (expense) benefit	(35)	4,074	—
Net loss	(33,093)	(47,582)	(36,766)
PREFERRED STOCK DIVIDENDS AND ACCRETION	—	—	(6,327)
BENEFICIAL CONVERSION FEATURE OF SERIES B, KBH AND C PREFERRED STOCK:	—	—	(50,180)
Net loss applicable to common shareholders	\$(33,093)	\$(47,582)	\$(93,273)
Net loss per common share, basic and diluted (Note 2)	\$ (1.45)	\$ (2.09)	\$ (8.55)
Shares used in computing basic and diluted net loss per common share (Note 2)	22,809	22,753	10,908

The accompanying notes are an integral part of these financial statements.

GENAISSANCE PHARMACEUTICALS, INC.

Statements of Stockholders' Equity and Comprehensive Loss
(Amounts in thousands)

	Common Stock Shares	Common Stock Amounts	Additional Paid-in Capital	Accumulated Deficit	Accumulated other comprehensive income (Loss)	Total Common Stockholders' Equity	Other Comprehensive Loss
Balance at December 31, 1999	2,810	\$ 3	\$ 4,819	\$ (19,654)	\$ —	\$(14,832)	
Issuance of common stock from exercise of stock options	113	—	452	—	—	452	
Issuance of common stock from exercise of warrants	98	—	230	—	—	230	
Compensation related to issuance of options to purchase common stock	—	—	4,936	—	—	4,936	
Warrants issued in connection with debt financing and preferred stock offering	—	—	3,320	—	—	3,320	
Accretion in carrying value of redeemable preferred stock	—	—	—	(6,327)	—	(6,327)	
Beneficial conversion feature of Series B, KBH and C preferred stock	—	—	50,180	(50,180)	—	—	
Conversion of preferred stock in connection with initial public offering	12,704	13	72,054	—	—	72,067	
Cashless exercise of warrants in connection with initial public offering	62	—	501	—	—	501	
Sale of common stock in connection with initial public offering, net of offering costs	6,900	7	82,033	—	—	82,040	
Net change in unrealized investment gain	—	—	—	—	54	54	\$ 54
Net loss	—	—	—	(36,766)	—	(36,766)	(36,766)
Total comprehensive loss	—	—	—	—	—	—	\$(36,712)
Balance at December 31, 2000	22,687	\$23	\$218,525	\$(112,927)	\$ 54	\$105,675	
Issuance of common stock from exercise of stock options	76	—	157	—	—	157	
Issuance of common stock from Employee Stock Purchase Plan	20	—	168	—	—	168	
Compensation related to issuance of options to purchase common stock	—	—	498	—	—	498	
Net change in unrealized investment gain	—	—	—	—	63	63	\$ 63
Net loss	—	—	—	(47,582)	—	(47,582)	(47,582)
Total comprehensive loss	—	—	—	—	—	—	\$(47,519)
Balance at December 31, 2001	22,783	\$23	\$219,348	\$(160,509)	\$117	\$ 58,979	
Issuance of common stock from exercise of stock options	10	—	—	—	—	—	
Issuance of common stock from Employee Stock Purchase Plan	54	—	53	—	—	53	
Compensation related to issuance of options to purchase common stock	—	—	12	—	—	12	
Net change in unrealized investment gain	—	—	—	—	(96)	(96)	\$ (96)
Net loss	—	—	—	(33,093)	—	(33,093)	(33,093)
Total comprehensive loss	—	—	—	—	—	—	\$(33,189)
Balance at December 31, 2002	22,847	\$23	\$219,413	\$(193,602)	\$ 21	\$ 25,855	

The accompanying notes are an integral part of these financial statements.

GENAISSANCE PHARMACEUTICALS, INC.

Statements of Cash Flows

(Amounts in thousands)

	Year Ended December 31,		
	2002	2001	2000
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(33,093)	\$(47,582)	\$(36,766)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	8,178	8,559	4,052
Impairment of fixed assets	6,000	—	—
Loss on disposal of equipment	—	—	55
Stock-based compensation	12	498	4,936
Accretion of interest	811	—	—
Non-cash interest expense	—	—	376
Warrants issued in exchange for services	—	—	14
Changes in assets and liabilities:			
Accounts receivable	(89)	(121)	(1,453)
State income tax receivable	1,000	(1,500)	—
Other assets	1,013	132	(407)
Accounts payable	(1,769)	(2,644)	4,431
Accrued expenses	(3,162)	2,788	1,623
Deferred revenue	2,609	(200)	1,878
Net cash used in operating activities	(18,490)	(40,070)	(21,261)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(70)	(4,304)	(8,702)
Investments in marketable securities	(9,629)	(42,697)	(45,118)
Proceeds from marketable securities	28,530	49,463	4,000
Net cash provided by (used in) investing activities	18,831	2,462	(49,820)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net proceeds from issuance of preferred stock	—	—	53,925
Net proceeds from issuance of common stock and from the exercise of options and warrants	53	325	682
Proceeds from initial public offering, net of issuance costs	—	—	82,040
Repayment of long-term debt, net	(703)	(863)	(1,061)
Proceeds from long-term debt due to related parties	—	364	3,854
Repayment of capital leases (net)	(6,217)	(6,218)	(2,821)
Increase in restricted cash	(2,100)	—	—
Net cash (used in) provided by financing activities	(8,967)	(6,392)	136,619
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(8,626)	(44,000)	65,538
CASH AND CASH EQUIVALENTS, beginning of period	25,204	69,204	3,666
CASH AND CASH EQUIVALENTS, end of period	\$ 16,578	\$ 25,204	\$ 69,204
SUPPLEMENTAL DISCLOSURE OF CASH FLOW ACTIVITIES:			
Cash paid for interest	\$ 1,777	\$ 2,630	\$ 1,308
Cash paid for income taxes	\$ 35	\$ —	\$ —
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:			
Conversion of liabilities into common or preferred stock	\$ —	\$ —	\$ 3,561
Acquisition of equipment pursuant to capital lease obligations	—	1,754	18,735
Issuance of warrants in connection with financing agreements	—	—	3,320
Conversion of preferred stock into common stock	—	—	72,067
Cashless exercise of warrants	—	—	501

The accompanying notes are an integral part of these financial statements.

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements
(Amounts in thousands, except per share data)

(1) ORGANIZATION AND OPERATIONS

Genaisance Pharmaceuticals, Inc. (the Company) is seeking to create personalized medicines through the integration of pharmacogenomics into drug development and marketing. The Company discovers inherited differences, or genomic markers, that exist in human genes. The Company uses its technological capabilities and methods as well as its clinical genetic development skills to identify the genomic markers that appear to define a patient population that responds best to a medication and has a superior safety profile. The Company markets its technology and its predictive genomic markers to the pharmaceutical and biotechnology industries as a means to improve the development, marketing and prescribing of drugs.

In addition to the normal risks associated with a business venture, there can be no assurance that the Company's technologies will be successfully used, that the Company will obtain adequate patent protection for its technologies, and that any products will be commercially viable. In addition, the Company operates in an environment of rapid change in technology and has substantial competition from companies developing genomic related technologies. The Company expects to incur substantial expenditures in the foreseeable future for its research and development and commercialization of its products. The Company's management believes, based upon its current business plan and existing financial resources that it will have the ability to fund its expected net losses, debt obligations and capital expenditures for at least 12 months.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Revenue recognition

The Company earns its revenues primarily through the licensing of its *HAP*[™] Technology and by *HAP*[™] Typing services. The Company has also entered into agreements which provide for future milestones and royalty payments. The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101), and in accordance with Statement of Position 97-2 (SOP 97-2), *Software Revenue Recognition*, as amended by Statement of Position 98-9 (SOP 98-9). In accordance therewith, the Company recognizes annual license and subscription fees over the term of the agreement and service fees as the services are performed. Future milestones and royalty payments, if any, will be recognized when received, provided that the milestone is substantive and a culmination of the earnings process has occurred. Amounts received in advance of revenue recognition are recorded as deferred revenue.

Revenue from Gene Logic, Inc., J&J PRD and Pfizer, Inc. accounted for 82% and 94% of the Company's total revenue in fiscal 2002 and 2001, respectively. Revenue from Gene Logic, J&J PRD and Visible Genetics accounted for 90% of the Company's total revenue in fiscal 2000. Revenue from each of these customers accounted for 10% or more of the Company's total revenue for 2002 and 2001, respectively.

Stock-Based Compensation

At December 31, 2002, the Company had one stock-based compensation plan, which is more fully described in Note 10 to the Financial Statements. The Company accounts for the plan under the recognition and measurement principles of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations. The Company has not issued

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

stock options or made modifications to existing stock options where the exercise price is less than the market value of the Company's common stock on the date of grant or modification.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation. For the years ended December 31, 2002, 2001 and 2000:

<u>Amounts in thousands, except per share data</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net Loss, as reported	\$(33,093)	\$(47,582)	\$(93,273)
Add: Stock-Based Employee Compensation Expense Included in Reported Net Loss	12	498	5,256
Deduct: Total Stock-Based Employee Compensation Expense Determined under Fair Value Based Method for All Awards	<u>(880)</u>	<u>(3,664)</u>	<u>(7,140)</u>
Pro Forma Net Loss	<u>\$(33,961)</u>	<u>\$(50,748)</u>	<u>\$(95,157)</u>
Net Income (Loss) Per Share:			
Basic and diluted—As Reported	<u>\$ (1.45)</u>	<u>\$ (2.09)</u>	<u>\$ (8.55)</u>
Basic and diluted—Pro Forma	<u>\$ (1.49)</u>	<u>\$ (2.23)</u>	<u>\$ (8.72)</u>

Other disclosures required by SFAS No. 123 have been included in Note 10.

Research and development

Expenditures for research and development are charged to expense as incurred.

Patent and licensed technology costs

The Company expenses the costs of obtaining patents and licensed technology until such point that the realization of the carrying value of these costs is reasonably assured.

Net loss per common share

The Company computes and presents net loss per common share in accordance with SFAS No. 128, *Earnings Per Share*. There is no difference in basic and diluted net loss per common share as the effect of convertible preferred stock, stock options and warrants would be anti-dilutive for all periods presented. The outstanding convertible preferred stock, stock options and warrants (prior to application of the treasury stock method) would entitle holders to acquire 3,990, 3,611 and 3,039 shares of common stock at December 31, 2002, 2001, and 2000, respectively.

Segment reporting

SFAS No. 131, *Disclosure about Segments of an Enterprise and Related Information* establishes annual and interim reporting standards for an enterprise's operating segments and related disclosures

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

about its products, services, geographic areas, and major customers. The Company has determined that it operates in only one segment. In addition, all revenues are generated from U.S. and Canadian entities, and all long-lived assets are maintained in the United States.

Valuation of long-lived assets

The Company accounts for its investments in long-lived assets in accordance with Statement of Financial Accounting Standards No. 144 (SFAS No. 144), *Accounting for the Impairment or Disposal of Long-Lived Assets and Long-Lived Assets*. SFAS No. 144 requires a company to review its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Factors the Company considers important, which could trigger an impairment review, include, among others, the following:

- a significant adverse change in the extent or manner in which a long-lived asset is being used;
- a significant adverse change in the business climate that could affect the value of a long-lived asset; and
- a significant decrease in the market value of assets.

If the Company determines that the carrying value of long-lived assets may not be recoverable, based upon the existence of one or more of the above indicators of impairment, the Company compares the carrying value of the asset group to the undiscounted cash flows expected to be generated by the group. If the carrying value exceeds the undiscounted cash flows, an impairment charge may be needed. To determine the amount of the impairment charge, the Company compares the carrying value of the applicable fixed asset group to its fair value. If the fair value is less than the carrying value, such amount is recognized as an impairment charge. (See Note 4)

Cash and cash equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

Software development costs

The Company enters into agreements to license its *HAP* Technology, including its *DecoGen*[®] Informatics System, to third parties. The Company evaluates the establishment of technological feasibility of its products in accordance with Statement of Financial Accounting Standards (SFAS) No. 86, *Accounting for the Costs of Computer Software to be Sold, Licensed or Otherwise Marketed*. The Company has developed a product for a market that is subject to rapid technological change, new product development, and changing customer needs. In addition, the ability to continue to market the product is contingent upon the Company's ability to successfully populate the database. The Company has concluded that technological feasibility is established when a product design and working model of the software product has been completed and the completeness of the working model and its consistency with the product design has been confirmed by testing. The time period during which costs could be capitalized from the point of reaching technological feasibility until the time of general product release is very short and, consequently, the amounts that could be capitalized are not material

GENAISSANCE PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

(Amounts in thousands, except per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

to the Company's financial position or results of operations. Therefore, the Company has charged all such costs to research and development in the period incurred.

Fair value of financial instruments

Financial instruments include cash and cash equivalents, receivables, marketable securities and long-term debt. Cash and cash equivalents and receivables approximate fair value and marketable securities are carried at fair value. Long-term debt is carried at cost, which management believes approximates fair value based upon recent borrowing rates obtained over the past twelve months.

Other comprehensive income (loss)

The Company presents its financial statements in accordance with SFAS No. 130, *Reporting Comprehensive Income*, which establishes standards for the reporting and displaying of comprehensive income and its components in a full set of general purpose financial statements. Accordingly, the Company has included this presentation as a component of the statements of stockholders' equity and comprehensive loss. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners ("comprehensive income"). The Company's other comprehensive income (loss) arises from net unrealized gains (losses) on marketable securities. The Company has elected to display comprehensive income (loss) as a component of the statement of stockholders' equity and comprehensive loss.

Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. (See Note 6)

Recently issued accounting standards

In June 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure, an amendment of FASB Statement No. 123*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value-based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. SFAS No. 148 is effective for fiscal years ending after December 15, 2002 for annual statements and for interim periods beginning after December 15, 2002 for interim financial reports. The Company has adopted the disclosure requirements of SFAS No. 148 in these financial statements, but has not determined whether or not it will voluntarily adopt SFAS No. 123 and the related transition alternatives pursuant to SFAS No. 148.

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146 (SFAS No. 146), *Accounting for Costs Associated with Exit or Disposal Activities*. This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. We believe the adoption of this new standard will not have a material impact on either the Company's operating results or financial position.

In November 2002 the FASB issued FASB Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (an Interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34). FIN 45 clarifies the requirements of FASB Statement No. 5 (FAS 5) *Accounting for Contingencies*, relating to a guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. FIN 45 requires that upon issuance of a guarantee, the guarantor must recognize a liability for the fair value of the obligation it assumes under that guarantee. The initial recognition and measurement provisions are effective for guarantees issued or modified after December 31, 2002. The disclosure requirements under FIN 45 are effective for the Company's fiscal 2002 year-end.

In November 2002, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. This issue addresses revenue recognition for arrangements with multiple deliverables which should be considered as separate units of accounting if the deliverables meet certain criteria as described in EITF 00-21. This issue is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Early application is permitted.

(3) MARKETABLE SECURITIES

The Company classifies its marketable securities as "available for sale" and, accordingly, carries these investments at their aggregate fair value. Unrealized gains or losses on these investments are included as a separate component of stockholders' equity (deficit) and comprehensive loss (See Note 2). The Company's marketable securities as of December 31, 2002 and 2001 consisted principally of corporate bonds. As of December 31, 2002, these securities had a maximum maturity of less than twelve months and carried a weighted average interest rate of approximately 2.06%. The amortized cost of these securities differed from their fair values by \$21 and \$117 as of December 31, 2002 and 2001, respectively.

(4) IMPAIRMENT OF FIXED ASSETS

During the year ended December 31, 2002, we determined that certain conditions had arisen which triggered the need to review our long-lived assets for potential impairment. The conditions included, but were not limited to, the overall business climate in which we operate and a significant change in the manner in which we were utilizing our DNA sequencing facility and related assets. Our review concluded that the carrying value of the long-lived assets exceeded their fair value by approximately \$6,000. The impairment charge includes the write-down of sequencing equipment, computer hardware

GENAISSANCE PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

(Amounts in thousands, except per share data)

(4) IMPAIRMENT OF FIXED ASSETS (Continued)

and software and leasehold improvements and has been allocated to the individual assets on a pro-rata basis. (See Note 2)

(5) PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2002	2001
Equipment, computers and software	\$ 5,541	\$ 6,684
Equipment under capital leases	11,296	25,988
Leasehold improvements and office equipment	8,559	9,080
	25,396	41,752
Less—accumulated depreciation and amortization	(10,842)	(13,244)
Total property and equipment, net	\$14,554	\$28,508

These assets are stated at cost and are being depreciated and amortized over the shorter of their lease term or their estimated useful lives on a straight-line basis as follows:

Equipment, computers and software	3-4 years
Office equipment	5 years
Leasehold improvements	remaining term of lease
Equipment under capital lease	3-5 years

Accumulated depreciation related to equipment under capital leases was \$5,168 and \$9,618 at December 31, 2002 and 2001, respectively.

Expenditures for maintenance and repairs, which do not improve or extend the useful lives of the respective assets, are expensed as incurred.

(6) ACCRUED CLINICAL TRIAL EXPENSES

Included in accrued expenses in the accompanying balance sheets is accrued clinical trial expenses which are comprised of amounts owed to third party Clinical Research Organizations (CRO) for research and development work performed on behalf of the Company. At each period end the Company evaluates the accrued clinical trial expense balance and, based upon information received from each CRO, ensures that the balance is appropriately stated. During the year ended December 31, 2002, the Company reversed previously accrued clinical trial expenses of \$1,400 and credited Research and Development expense. This resulted in a net credit of \$717 for clinical trial expenses for the year ended December 31, 2002. As of December 31, 2002, based on the information available, the Company does not believe that there is any additional liability to each CRO.

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(7) FINANCING ARRANGEMENTS

Long-term debt consists of the following:

	December 31,	
	2002	2001
Notes payable to Connecticut Innovations, Inc. (CII) bearing interest at 6.5%, payments of interest only for a defined period and monthly payments of principal and interest thereafter.	\$4,898	\$5,116
Note payable to TransAmerica Business Corp. (TBCC) bearing interest at 12.98%, monthly payments of principal and interest of \$72 are payable through August 2002.	—	485
Total long-term debt	4,898	5,601
Less—current portion	(397)	(672)
Total long-term debt, less current portion	<u>\$4,501</u>	<u>\$4,929</u>

The Company has entered into financing agreements (the Agreements) with Connecticut Innovations, Inc. (CII), a stockholder of the Company, to finance certain leasehold improvements and other costs associated with the Company's facility expansion. The Agreements provide for interest only for a certain period with principal payments based on a 120 month amortization beginning April 2001 through October 2002, with final balloon payments due in March 2009 through June 2011. Borrowings under the Agreements are secured by the related leasehold improvements.

Aggregate future maturities of the notes payable are as follows:

Year Ended December 31	
2003	\$ 397
2004	425
2005	453
2006	483
2007	515
Thereafter	<u>2,625</u>
	<u>\$4,898</u>

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(8) CAPITAL LEASES

Capital lease obligations related to equipment consist of the following:

	December 31,	
	2002	2001
Capital lease obligations to Finova Capital Credit Corp. originally payable in varying installments through August 2004, bearing interest from 8.15% to 10.07%, secured by the related equipment.	\$ 7,207	\$ 9,725
Capital lease obligations to Newcourt Financial USA, Inc. payable in varying installments through November 2003, bearing interest from 10.5% to 11.8%, secured by the related equipment.	517	1,052
Capital lease obligations to General Electric Capital Corporation (Oxford Venture Finance LLC) originally payable in varying installments through February 2005, bearing interest from 10.85% to 12.46%, secured by the related equipment.	3,177	5,112
Capital lease obligation to IBM Credit Corp., payable in varying installments through October 2003 bearing interest at 11.77%, secured by the related equipment	286	661
Other	—	43
Total capital lease obligations	\$11,187	\$16,593

In December 2002, the Company announced it received a notice from GE claiming that an event of default had occurred under the lease agreement as a result of an alleged material adverse change in the Company's business. Because of the alleged default, GE declared that all principal and future interest obligations were due and payable immediately. GE also filed a complaint in the Superior Court of the State of Connecticut, demanding payment of all amounts due under the lease agreements. The Company also received a notice from Finova, stating that as a result of the alleged default claim by GE, there had been a cross-default under the Company's agreement with Finova. To remedy the cross-default, Finova declared that all principal and future interest obligations were due and payable immediately. On March 12, 2003, the Company settled the claim with GE and simultaneously amended its lease agreement (GE Amendment). In connection with the GE Amendment, and as additional security for its payment obligations to GE, the Company delivered to GE a \$2,000 irrevocable letter of credit and agreed to additional covenants. The Company may cause the letter of credit to be adjusted on a quarterly basis commencing October 1, 2003 based on a decrease in outstanding amounts due GE, as defined. The letter of credit is collateralized by cash at 105% of the outstanding letter of credit balance. In connection with the amendment, GE retroactively rescinded their default claim and both parties have withdrawn from any legal action. The GE Amendment and letter of credit have been retroactively reflected in the accompanying financial statements as of December 31, 2002. The Company has not entered into a settlement agreement with Finova. The Company has recorded an additional charge to interest expense for future interest due under the capital lease agreement with Finova to reflect the fact that all future interest and principal is currently due and payable under the Finova capital lease agreement as a result of the default claim. The amounts due to GE and Finova have been classified as current obligations as in the accompanying balance sheet as of December 31, 2002, as a result of continuing material adverse change provisions within the GE lease agreement and as a result of the Finova default claim.

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(8) CAPITAL LEASES (Continued)

In addition to the principal payments due under the capital lease agreements, the Company is obligated to make interest payments over the term of the lease. As of December 31, 2002, the Company is obligated to pay \$342 in interest over the remaining term of the lease agreements with GE, Newcourt and IBM.

The majority of the Company's capital lease arrangements allow for the purchase of the related equipment at the completion of the lease term as defined in the agreement. Certain of the capital lease agreements require the purchase of the equipment at the completion of the lease term. The required purchase obligations are included in the capital lease obligations above.

(9) PREFERRED STOCK

In March 2000, the Company sold 1,539 shares of Series C Redeemable Convertible Preferred Stock (Series C) at \$8.25 per share resulting in proceeds of \$11,883, net of issuance expenses of \$817.

In February and March 2000, the Company sold 8,728 shares of Series B and Series KBH Redeemable Convertible Preferred Stock (collectively, Series B) for \$5.50 per share resulting in proceeds of \$42,042, net of cash issuance costs of \$2,375 and net of the conversion of \$3,500 of convertible promissory notes, and related interest, which were issued in 1999 (Note 9) and which were converted into 636 shares of Series B based upon a per share conversion price of \$5.50 per share. In connection with this offering, the investment banker was issued a warrant (which is exercisable through February 2005) to purchase 400 shares of common stock at \$6.05 per share (See Note 10). The Company recorded additional issuance costs of \$2,892, which approximated the fair value of the warrant at the date of issuance.

Upon the completion of the Company's initial public offering in August 2000, all preferred stock was automatically converted into 12,704 shares of common stock.

While outstanding, the Company's Series A, B and C shares (collectively, the Preferred) earned dividends at 8% per annum. In addition, the holders of the Preferred had certain rights which could have required that the Company repurchase such shares, commencing in 2005, at the greater of the original purchase price plus accrued but unpaid dividends or fair value, as defined. As a result of such dividend and redemption rights, during 2000, the Company recognized \$6,327 of accretion in the carrying value of the redeemable preferred stock which is reflected in the accompanying 2000 statements of stockholders' equity (deficit) and comprehensive loss.

As a result of the Company's initial public offering, dividends earned subsequent to the Series B and C issuance dates were no longer required to be paid. Included in the accompanying balance sheets is \$1,159 of accrued dividends earned on the Series A prior to the issuance of the Series B and C, which continue to be payable. The Company has classified accrued dividends as a current liability in the financial statements for the year ended December 31, 2002, as the Company may be contractually obligated to pay such dividends within the next 12 months.

In connection with the sale of Series B and C, the Company also recorded a charge to accumulated deficit of \$50,180, which represented the beneficial conversion feature of this stock. This amount was accounted for in 2000 as a dividend to these preferred stockholders and as a result,

GENAISSANCE PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

(Amounts in thousands, except per share data)

(9) PREFERRED STOCK (Continued)

increased the Company's paid in capital, net loss applicable to common shareholders and the related net loss per common share.

(10) COMMON STOCK, STOCK OPTIONS AND WARRANTS

Common Stock

At December 31, 2002, the Company has authorized 58,000 shares of common stock. As of December 31, 2002, 4,787 shares have been reserved for issuance under warrants and the Company's stock options and employee stock purchase plans.

In August 2000, the Company issued 6,900 shares of common stock in connection with its initial public offering.

Stock option plan

In 1993, the Board of Directors and stockholders approved the Stock Option Plan (as amended, the Plan) which provides for both incentive and nonqualified stock options. As of December 31, 2002, under the terms of the Plan, stock options may be granted for up to a maximum of 4,287 shares. Options granted under the Plan are exercisable for a period determined by the Company, but in no event longer than ten years from date of grant. In the event of certain capital stock changes, the options are subject to adjustment in accordance with anti-dilution provisions.

The Company has adopted the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. This pronouncement requires the measurement of the fair value of stock options to be included in the statement of operations or disclosed in the notes to financial statements. The Company accounts for stock-based compensation for employees under Accounting Principles Board Opinion No. 25 and has elected the disclosure-only alternative under SFAS No. 123.

A summary of the status of the Company's stock option plan at December 31, 2002, 2001 and 2000 and changes during the periods then ended is presented below:

	2002		2001		2000	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding, January 1	3,084	\$8.06	2,512	\$8.58	990	\$2.37
Granted	939	2.09	788	6.24	1,691	11.82
Cancelled or expired	(550)	9.02	(140)	10.32	(56)	5.03
Exercised	(10)	.01	(76)	2.05	(113)	4.02
Outstanding, December 31	<u>3,463</u>	\$6.31	<u>3,084</u>	\$8.06	<u>2,512</u>	\$8.58
Options exercisable at December 31	<u>1,643</u>	\$6.55	<u>1,385</u>	\$7.11	<u>836</u>	\$4.83
Weighted average fair value of options granted during the year		\$1.77		\$5.58		\$6.26

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(10) COMMON STOCK, STOCK OPTIONS AND WARRANTS (Continued)

The following table summarizes information about stock options at December 31, 2002:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.01-\$1.50	729	8.27	\$ 1.02	285	\$ 1.25
\$1.51-\$3.00	734	6.94	\$ 2.75	499	\$ 2.82
\$3.01-\$8.25	799	8.58	\$ 5.08	265	\$ 5.29
\$8.26-\$12.51	1,072	7.36	\$11.82	532	\$11.79
\$12.52-\$32.20	129	7.80	\$18.26	72	\$18.70
	<u>3,463</u>	<u>7.76</u>	<u>\$ 6.31</u>	<u>1,653</u>	<u>\$ 6.51</u>

During 2002, 2001 and 2000, options to purchase 826, 703 and 1,362 shares, respectively, of common stock were granted at an exercise price equal to the fair value of the common stock on the date of grant at weighted average exercise prices of \$1.65, \$6.00 and \$12.80, respectively, per share. The weighted average fair value of these options at the date of grant, as prescribed by SFAS No. 123 was \$1.36, \$4.86 and \$7.77 during 2002, 2001 and 2000, respectively. In addition, during 2002, options to purchase 113 shares of common stock were granted at an exercise price greater than the fair value of the common stock on the date of grant at a weighted average exercise price of \$5.31 per share. During 2001 and 2000, options to purchase 85 and 329 shares, respectively, of common stock were granted at an exercise price less than the fair value of the common stock on the date of grant at weighted average exercise prices of \$8.25 and \$7.77, respectively, per share. The weighted average fair values of these options at the date of grant, as prescribed by SFAS No. 123 was \$2.67, \$11.42 and \$5.78 during 2002, 2001 and 2000, respectively.

Total compensation (benefit) expense recorded in the accompanying statements of operations associated with employee stock options is \$(104), \$391 and \$381 for the years ended December 31, 2002, 2001 and 2000, respectively. Unamortized compensation expense associated with outstanding stock options at December 31, 2002 is approximately \$329.

The Company accounts for options granted to consultants, which include scientific advisory board members, using the Black-Scholes method prescribed by SFAS No. 123 and in accordance with Emerging Issues Task Force Consensus No. 96-18. During the year ended December 31, 2000, the Company elected to fully vest all unvested options previously granted to scientific advisory board members. Accordingly, the Company recorded a compensation charge in the quarter ended March 31, 2000 based upon the incremental fair value and previously recognized compensation expense associated with these options at the time of vesting. Total compensation expense recorded in the accompanying statements of operations associated with these consultant options is \$116, \$107 and \$1,675 for the years ended December 31, 2002, 2001 and 2000, respectively.

In 1996, in connection with a change in management of the Company, the Company's current Vice Chairman and Chief Executive Officer (the Officers) entered into a stock purchase agreement (Officer Stock Purchase Agreement) with a then officer and major shareholder of the Company (Former CEO).

GENAISSANCE PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

(Amounts in thousands, except per share data)

(10) COMMON STOCK, STOCK OPTIONS AND WARRANTS (Continued)

The Officer Stock Purchase Agreement permitted the Officers to purchase shares of common stock from the Former CEO in exchange for notes payable aggregating \$320 (Officer Stock Notes). The notes were collateralized by the stock and were payable at the earlier of August 31, 2001 or an initial public offering or change in control, as defined. The Company recognized this transaction as a compensatory arrangement between the Company and the Officers and accordingly recognized a non-cash compensation expense of \$2,880 in 2000.

In 2000, upon successful completion of the initial public offering, the Company's board of directors elected to assume the \$320 of Officer Stock Notes. The Company recognized compensation expense of \$320 during 2000 as a result of the assumption of such Officer Stock Notes. Such forgiveness is included in stock based compensation in the accompanying statement of operations.

The Company has computed the pro forma disclosures required under SFAS No. 123 for options granted to employees using the Black-Scholes option pricing model. The weighted average assumptions used are as follows:

	2002	2001	2000
Risk-free interest rate	3.81%	4.24%	6.1%
Expected dividend yield	None	None	None
Expected lives	5 years	5 years	7 years
Expected volatility	116%	117%	0% and 145%

Had compensation cost for the Company's stock option plan been determined consistent with SFAS No. 123, the Company's pro forma net loss would have been as follows:

	For the Years Ended December 31,		
	2002	2001	2000
Net (loss) applicable to common stockholders:			
As reported	\$(33,093)	\$(47,582)	\$(93,273)
Pro forma	(33,961)	(50,748)	(95,157)
Net (loss) per common share, basic and diluted:			
As reported	(1.45)	(2.09)	(8.55)
Pro forma	(1.49)	(2.23)	(8.72)

Employee stock purchase plan

During fiscal 2000, the board of directors adopted the Employee Stock Purchase Plan 2000 (ESPP). Under the ESPP, eligible employees may purchase common stock at not less than 85% of fair value, as defined. Under the ESPP, the Company's compensation committee grants rights to purchase the shares under the ESPP. The Company has reserved 250 shares of common stock for issuance under the ESPP. As of December 31, 2002, 74 shares have been issued under the ESPP.

Stock warrants

The Company has historically issued warrants in connection with certain of its financing and capital raising activities.

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(10) COMMON STOCK, STOCK OPTIONS AND WARRANTS (Continued)

As of December 31, 2002, the Company had warrants outstanding to purchase 527 shares of common stock of the Company at a weighted average exercise price of \$6.08. The warrants expire from November 2003 through April 2006. Certain warrants include anti-dilutive provisions, as defined.

(11) INCOME TAXES

The Company accounts for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes*. This statement requires the Company to recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been previously recognized in the Company's financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and the tax bases of the assets and liabilities and the net operating loss carryforwards available for tax reporting purposes, using applicable tax rates for the years in which the differences are expected to reverse.

The reconciliation of the statutory Federal income tax rate to the Company's effective income tax rate for the years ended December 31, 2002, 2001 and 2000, is as follows:

	For the Years Ended December 31,		
	2002	2001	2000
Statutory rate	34.0%	34.0%	34.0%
State tax benefit, net of Federal taxes	5.9	12.6	4.9
Other	2.1	(1.0)	2.0
Increase in deferred tax valuation allowance	(42.0)	(37.7)	(40.9)
	<u>—%</u>	<u>7.9%</u>	<u>—%</u>

The Company has available, at December 31, 2002, unused net operating loss carryforwards of approximately \$121.1 and \$120.1 which may be available to offset future Federal and state taxable income, respectively, if any. The future utilization of these carryforwards may be limited on a permanent basis due to changes within the Company's current and future ownership structure as defined within the internal revenue code. Federal carryforwards are scheduled to expire beginning in 2007. State carryforwards are scheduled to expire from 2003 through 2021.

As a result of legislation passed in the State of Connecticut which provided companies with the opportunity to exchange certain research and development tax credit carryforwards for a cash payment in exchange for foregoing the carryforward of the research and development credits at a rate of 65% of the annual incremental research and development tax credit, as defined. During 2001, the Company filed a claim to exchange its 2000 incremental research and development credit and, as a result, recognized a state income tax benefit of approximately \$2,600. In addition, during 2001, the Company recorded an income tax receivable of \$1,500 for the estimated proceeds from the 2001 research and development tax credit. The State of Connecticut rescinded the legislation during 2002.

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(11) INCOME TAXES (Continued)

The components of deferred income tax assets as of December 31, 2002 and 2001 are as follows:

	For the Years Ended December 31,	
	2002	2001
Deferred tax assets:		
Net operating loss carryforwards and tax credits	\$52,606	\$ 40,816
Other	4,882	2,256
Total deferred tax assets	57,488	43,072
Less—valuation allowance for deferred tax assets	(57,488)	(43,072)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company has not yet achieved profitable operations. Accordingly, management believes the tax benefits as of December 31, 2002 do not satisfy the realization criteria set forth in SFAS No. 109 and has recorded a valuation allowance for the entire deferred tax asset.

(12) COMMITMENTS AND CONTINGENCIES

401(k) retirement plan

The Company has a 401(k) defined contribution retirement plan covering substantially all full-time employees. The Company provides a matching cash contribution of 25% of employee contributions, up to 8% of employee compensation. The Company contributed \$120, \$122 and \$60 to the plan during 2002, 2001 and 2000, respectively.

Royalty and other commitments

The Company periodically enters into agreements with third parties to obtain exclusive or non-exclusive licenses for certain technologies management believes important to the Company's overall business strategy. The terms of certain of these agreements provide for the Company to pay future royalty payments based on product sales or sublicense income generated from the applicable technologies, if any. Additionally, certain agreements call for future payments upon achievement of certain milestones. The aggregate future annual minimum payments (assuming non-termination of these agreements) for fiscal 2003, 2004, 2005, 2006 and 2007 are \$88, \$103, \$103, \$103 and \$103, respectively. The Company recorded expenses of \$3,205, \$4,728 and \$2,417 during 2002, 2001 and 2000, respectively.

In connection with the Company's initial license of a patent from a University, the Company is obligated to pay both the University and the inventor of the technology a sublicense royalty fee. The inventor of the technology subsequently joined the Company and is currently the Vice Chairman of the Company. The Company receives royalty revenue under this patent from a third party (Licensor). Future royalty revenue from the Licensor, if any, will be subject to a sublicense royalty fee. The Company has elected to recognize this expense as incurred. Included in the accompanying statements of operations for the years ended December 31, 2002, 2001 and 2000, are \$42, \$54 and \$530, respectively, of related sublicensing fees.

GENAISSANCE PHARMACEUTICALS, INC.
Notes to Financial Statements (Continued)
(Amounts in thousands, except per share data)

(12) COMMITMENTS AND CONTINGENCIES (Continued)

Operating leases

The Company leases its operating facilities located in New Haven, Connecticut. The lease agreements require annual lease payments of \$816 per year increasing to \$1,100 per year over five years terminating in 2006. The Company has two five-year renewal options to extend the lease beyond its initial term. The Company is recording the expense associated with the lease on a straight-line basis over the expected ten-year minimum term of the lease.

In addition to the five-year operating lease for the Company's current facility, the Company also has operating leases for various office equipment.

Rental expense for all operating leases for the years ended December 31, 2002, 2001 and 2000 was \$1,168, \$1,055 and \$549, respectively.

Future minimum payments under all non-cancelable operating leases in effect as of December 31, 2002 are as follows:

2003	\$1,178
2004	1,149
2005	1,086
2006	1,013
2007	1,012
Thereafter	3,792

(13) LEGAL MATTERS

The Company, from time to time, has been subject to legal claims arising in connection with its business. While the ultimate results of the legal claims cannot be predicted with certainty, at December 31, 2002, other than default claims on capital lease obligations (See Note 8) there were no asserted claims against the Company which, in the opinion of management, if adversely decided would have a material adverse effect on the Company's financial position and cash flows.

(14) SIGNIFICANT CUSTOMERS AND FOREIGN BASED REVENUES

For the years ended December 31, 2002, 2001 and 2000 approximately 4%, 6% and 34%, respectively, of the Company's revenues resulted from foreign based customers. For the years ended December 31, 2002, 2001 and 2000, 82%, 94% and 90%, of revenues resulted from transactions with three customers.

GENAISSANCE PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

(Amounts in thousands, except per share data)

(15) QUARTERLY DATA—UNAUDITED

	2002			
	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter
Revenues	\$ 1,851	\$ 1,933	\$ 1,754	\$ 2,573
Operating expenses	10,739	15,186	6,668	6,146
Operating loss	(8,888)	(13,253)	(4,914)	(3,573)
Net loss applicable to common shareholders	(9,060)	(13,463)	(5,210)	(5,360)
Net loss per common share:				
Basic and diluted	(0.40)	(0.59)	(0.23)	(0.23)

	2001			
	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter
Revenues	\$ 997	\$ 1,069	\$ 1,083	\$ 2,196
Operating expenses	12,958	14,741	15,629	14,992
Operating loss	(11,961)	(13,672)	(14,546)	(12,796)
Net loss applicable to common shareholders	(11,192)	(13,209)	(11,801)	(11,380)
Net loss per common share:				
Basic and diluted	(0.49)	(0.58)	(0.52)	(0.50)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

The information required with respect to changes in the Company's accountants was previously reported in the Current Report on Form 8-K of the Company, filed on June 5, 2002, and is incorporated by reference into this Annual Report on Form 10-K.

PART III

Items 10, 11, 12, 13 and 15 of Part III (except for information required with respect to our executive officers which is set forth under "Executive Officers" in Item 1A of Part I of this report) have been omitted from this report, since we expect to file with the Securities and Exchange Commission, not later than 120 days after the close of our fiscal year, a definitive proxy statement. The information required by Items 10, 11, 12, 13 and 15 of this report, which will appear in the definitive proxy statement, is incorporated by reference into Part III of this report.

ITEM 14. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on their evaluation of the Company's disclosure controls and procedures (as defined in rules 13a-14(c) and 15d-14(c) promulgated under the Securities and Exchange Act of 1934, as amended (the "Exchange Act")), as of a date within 90 days of the filing date of this Annual Report on Form 10-K, the Company's chief executive officer and chief financial officer have concluded that the Company's disclosure controls and procedures are designed to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and are operating in an effective manner.

Changes in internal controls. There were no significant changes in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

PART IV

ITEM 16. EXHIBITS, FINANCIAL STATEMENT SCHEDULE AND REPORTS ON FORM 8-K

(a) 1. FINANCIAL STATEMENTS

The financial statements are listed under Item 8 of this report.

2. FINANCIAL STATEMENT SCHEDULES

The financial statement schedules listed under Item 8 of this report are omitted because they are not applicable or required information and are shown in the financial statements or the footnotes thereto.

(b) REPORTS ON FORM 8-K

No reports on Form 8-K were filed during the fourth quarter of 2002.

(c) EXHIBITS

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
3.1(1)	Amended and Restated Certificate of Incorporation.
3.3(2)	Amended and Restated By-Laws.
4.1(3)	Form of Common Stock Certificate.
4.2(3)	Form of Common Stock Purchase Warrant, together with a list of warrant holders.
10.1*(8)	2000 Amended and Restated Equity Incentive Plan as amended.
10.1A*(3)	Stock Option Plan.
10.2*(3)	Employee Stock Purchase Plan 2000.
10.3(3)	Form of Indemnification Agreement between Genaissance and its directors.
10.4(3)	Lease Agreement between Genaissance and Science Park Development Corporation dated September 15, 1998.
10.5(3)	Amendment No. 1 to Lease Agreement between Genaissance and Science Park Development Corporation dated December 1, 1999.
10.6(3)	Amendment No. 2 to Lease Agreement between Genaissance and Science Park Development Corporation dated December 16, 1999.
10.7*(3)	Genaissance 401(k) Plan
10.8(3)+	Collaboration Agreement between Genaissance and Telik, Inc. dated February 11, 1998.
10.9(3)	First Amendment, dated February 11, 1999, to the Collaboration Agreement between Genaissance and Telik, Inc. dated February 11, 1998.
10.10(3)+	License Agreement between Genaissance and Visible Genetics, Inc. dated November 21, 1996.
10.11(3)+	Patent License Amending Agreement between Genaissance and Visible Genetics, Inc. dated March 16, 2000.
10.12(3)	Loan Agreement between Genaissance and Connecticut Innovations, Incorporated dated September 15, 1998.
10.13(3)	Loan Agreement between Genaissance and Connecticut Innovations, Incorporated dated December 1, 1999.
10.14(3)	Master Lease Agreement between Genaissance and Finova Technology Finance dated October 2, 1998, and attached Schedules.
10.15(3)	Letter Agreement with Finova Capital Corporation dated January 24, 2000.
10.16(3)	Master Equipment Lease Agreement between Genaissance and Oxford Venture Finance dated June 10, 1999, and attached Schedules.
10.17(3)	Master Lease Agreement between Genaissance and Newcourt Financial USA Inc. dated March 26, 1999, and attached Schedules.
10.18*(3)	Employment Agreement with Gualberto Ruano dated August 24, 1998.
10.19*(3)	Employment Agreement with Kevin Rakin dated August 24, 1998.
10.20*(3)	Employment Agreement with Gerald F. Vovis dated April 15, 1999.
10.21*(3)	Confidentiality and Non-Competition Agreement with Richard Judson dated November 16, 1999.
10.22(3)+	Strategic Alliance Agreement between Genaissance and Sequenom, Inc. dated as of May 3, 2000.
10.23(3)	Letter Agreement with Finova Capital Corporation dated June 7, 2000.
10.24(3)	Letter Agreement with Connecticut Innovations, Incorporated dated June 2, 2000.
10.25(3)+	Collaboration Agreement with Gene Logic, Inc. dated June 28, 2000.
10.26(3)	Second Amended and Restated Registration Rights Agreement with the purchasers of Series A and Series KBL Non-voting Preferred Stock dated March 10, 2000.

EXHIBIT
NUMBER

DESCRIPTION OF DOCUMENT

-
- | | |
|-----------|--|
| 10.27(3) | Amended and Restated Registration Rights Agreement with the purchasers of Series B and Series KBH Preferred Stock dated March 10, 2000. |
| 10.28(3) | Registration Rights Agreement with purchasers of Series C Preferred Stock dated March 10, 2000. |
| 10.29(3) | Amendment No. 3 to Lease Agreement between Genaissance and Science Park Development Corporation dated June 1, 2000. |
| 10.30(3) | Purchase Agreement with Connecticut Innovations, Incorporated dated March 10, 1994. |
| 10.31(3) | Financing Agreement with Connecticut Innovations, Incorporated dated November 16, 1994. |
| 10.32(3) | Financing Agreement with Connecticut Innovations, Incorporated dated September 10, 1996. |
| 10.33(3) | Agreement Concerning Conversion of Convertible Note and Connecticut Presence with Connecticut Innovations, Incorporated dated August 24, 1998. |
| 10.34(3) | Supplemental Agreement to Agreement Concerning Conversion of Convertible Note and Connecticut Presence with Connecticut Innovations, Incorporated dated November 23, 1999. |
| 10.35(3) | Letter Agreement with Connecticut Innovations, Incorporated dated February 17, 2000. |
| 10.36(3) | Loan and Security Agreement and Promissory Note with Transamerica Business Credit Corporation dated April 30, 1999. |
| 10.37*(4) | Employment Agreement with Kenneth B. Kashkin dated September 13, 2000. |
| 10.38*(4) | Promissory Note with Gualberto Ruano dated August 7, 2000. |
| 10.39*(4) | Promissory Note with Kevin Rakin dated August 7, 2000. |
| 10.40(5)+ | Collaboration Agreement with Janssen Research Foundation dated November 22, 2000. |
| 10.41(5) | Third Loan Agreement with Connecticut Innovations, Incorporated dated July 26, 2000. |
| 10.42(6)+ | Agreement with Pfizer Inc. dated August 29, 2001. |
| 10.43(6)+ | HAP™ Focus Trial License Agreement with AstraZeneca UK Limited dated as of November 29, 2001. |
| 10.44(6)+ | Mednostics™ Collaboration and License Agreement with Biogen, Inc. dated as of January 31, 2002. |
| 10.45(6)+ | International Sales Representative Agreement with Intec Web and Genome Informatics Corporation dated as of February 4, 2002. |
| 10.46(6)+ | Amendment, dated December 27, 2001, to Collaboration Agreement with Gene Logic, Inc. dated June 28, 2000. |
| 10.47(6)+ | HAP™ Focus Trial License Agreement with Biogen, Inc. dated December 21, 2001. |
| 10.48(6) | Form of Registration Rights Agreement Waiver dated February 18, 2002. |
| 10.49*(6) | Employment Agreement with Richard Judson dated November 20, 2001. |
| 10.50(6) | Fourth Amendment to Lease between Science Park Development Corporation and Genaissance dated September 30, 2001. |
| 10.51(6) | Amendment, dated May 13, 2002, to Agreement with Pfizer Inc. dated August 29, 2001. |
| 10.52* | First Amendment, dated September 1, 2002, to Employment Agreement with Gualberto Ruano dated August 24, 1998. Filed herewith. |
| 10.53* | First Amendment, dated September 1, 2002, to Employment Agreement with Kevin Rakin dated August 24, 1998. Filed herewith. |
| 10.54+ | Amendment, dated November 22, 2002, to Collaboration Agreement with Janssen Research Foundation dated November 22, 2000. Filed herewith. |
| 10.55+ | Amendment, dated December 18, 2002, to Mednostics™ Collaboration and License Agreement with Biogen, Inc. dated as of January 31, 2002. Filed herewith. |
| 10.56+ | Agreement with Pharmacia & Upjohn Company dated December 12, 2002. Filed herewith. |

**EXHIBIT
NUMBER****DESCRIPTION OF DOCUMENT**

10.57+	Training and License Agreement with Becton, Dickinson and Company dated December 18, 2002. Filed herewith.
16.1(7)	Letter from Arthur Andersen LLP to the Securities and Exchange Commission, dated June 5, 2002.
23.1	Consent of PricewaterhouseCoopers LLP. Filed herewith.
99.1	Statement pursuant to 18 U.S.C. Section 1350. Filed herewith.
99.2	Statement pursuant to 18 U.S.C. Section 1350. Filed herewith.

* Indicates a management contract or compensatory plan.

+ Confidential treatment requested as to certain portions, which portions have been filed separately with the Commission.

- (1) Filed as Exhibit 3.2 to Genaissance's Registration Statement on Form S-1 (File No. 333-35314) and incorporated herein by reference.
- (2) Filed as Exhibit 3.4 to Genaissance's Registration Statement on Form S-1 (File No. 333-35314) and incorporated herein by reference.
- (3) Filed as an exhibit with the same number to Genaissance's Registration Statement on Form S-1 (File No. 333-35314) and incorporated herein by reference.
- (4) Filed as an exhibit to Genaissance's Quarterly Report on Form 10-Q (File No. 000-30981) for the quarter ended September 30, 2000 and incorporated herein by reference.
- (5) Filed as an exhibit to Genaissance's Annual Report on Form 10-K (File No. 000-30981) for the year ended December 31, 2000 and incorporated herein by reference.
- (6) Filed as an exhibit to Genaissance's Annual Report on Form 10-K (File No. 000-30981) for the year ended December 31, 2001 and incorporated herein by reference.
- (7) Filed as an exhibit to Genaissance's Current Report on Form 8-K (File No. 000-30981) filed with the SEC on June 4, 2002 and incorporated herein by reference.
- (8) Filed as an exhibit to Genaissance's Quarterly Report on Form 10-Q (File No. 000-30981) for the quarter ended June 30, 2002 and incorporated herein by reference.

CERTIFICATIONS

I, Kevin Rakin, certify that:

1. I have reviewed this annual report on Form 10-K of Genaissance Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 31, 2003

/s/ KEVIN RAKIN

Kevin Rakin

President and Chief Executive Officer

CERTIFICATIONS

I, Joseph Keyes, certify that:

1. I have reviewed this annual report on Form 10-K of Genaissance Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 31, 2003

/s/ JOSEPH KEYES

Joseph Keyes

Vice President and Chief Financial Officer

BOARD OF DIRECTORS

Jürgen Drews, M.D.

Chairman
Genaissance Pharmaceuticals, Inc.
Managing Partner
Bear Stearns Health Innoventure Fund LLC

Harry H. Penner, Jr.

Chairman and Chief Executive Officer
Nascent Bioscience, LLC

Kevin Rakin

President and Chief Executive Officer
Genaissance Pharmaceuticals, Inc.

Gualberto Ruaño, M.D., Ph.D.

Vice Chairman and Chief Scientific Officer
Genaissance Pharmaceuticals, Inc.

Seth Rudnick, M.D.

General Partner
Canaan Partners

Christopher Wright

Managing Director
Dresdner Kleinwort Capital

ADVISORY BOARD

Baruch S. Blumberg, M.D., Ph.D.

(Nobel Laureate)
Distinguished Scientist, Fox Chase Cancer Center
Professor, Medicine and Anthropology
Fox Chase Cancer Center, Philadelphia and
University of Pennsylvania

Fritz R. Bühler, M.D.

Managing Partner
Bear Stearns Health Innoventure Fund LLC
Director, European Center of Pharmaceutical Medicine

Stephen Dellaporta, Ph.D.

Professor, Molecular, Cellular and Developmental Biology
Yale University

Martin E. Kreitman, Ph.D.

Professor, Ecology and Evolutionary Biology
University of Chicago

Stephen B. Liggett, M.D.

Professor, Medicine, Molecular Genetics and Pharmacology
University of Cincinnati

Alexandros Makriyannis, Ph.D.

Professor, Molecular and Cell Biology
Director, Drug Discovery Institute
University of Connecticut

Anil Malhotra, M.D.

Associate Director, Psychiatry Research
Associate Professor, Psychiatry
The Zucker Hillside Hospital, NY and Albert Einstein
College of Medicine, NY

Richard M. Myers, Ph.D.

Professor, Genetics
Director, Stanford Human Genome Center
Stanford University

Neil Risch, Ph.D.

Professor, Genetics
Stanford University

Martin H. Schultz, Ph.D.

Arthur K. Watson Professor, Computer Science
Yale University

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CORPORATE INFORMATION

Investor Relations Contact:
Rhonda Chiger
Rx Communications Group, LLC
917-322-2569

Web Site:
www.genaissance.com

Transfer Agent:
American Stock Transfer and Trust Company
59 Maiden Lane
New York, NY 10038

Auditors:
PricewaterhouseCoopers LLC
100 Pearl Street
Hartford, CT 06103

Outside Counsel – Legal:
Hale and Dorr LLP
60 State Street
Boston, MA 02109

Outside Counsel – Patent:
Morgan & Finnegan
345 Park Avenue
New York, NY 10154

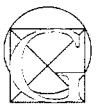
Stock Listing:
GNSC on Nasdaq National Market

Holders of Record:
As of March 14, 2003, there were approximately 279 stockholders of record of our Common Stock, one of which is Cede & Co., a nominee for the Depository Trust Company (DTC). All of the shares of Common Stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are, therefore, considered to be held of record by Cede & Co. as one stockholder.

Annual Meeting:
May 21, 2003, 10:00 a.m.
Genaissance Pharmaceuticals, Inc.
5 Science Park
New Haven, CT 06511

Common Stock Price Range:
Our common stock began trading on August 2, 2000, and the high and low sale prices as reported by Nasdaq, for the periods indicated, were as follows:

	High	Low
2001		
First Quarter	\$17.50	\$ 5.50
Second Quarter	\$14.04	\$ 7.69
Third Quarter	\$12.92	\$ 3.89
Fourth Quarter	\$ 5.99	\$ 2.90
2002		
First Quarter	\$4.58	\$2.47
Second Quarter	\$2.68	\$1.32
Third Quarter	\$1.35	\$0.46
Fourth Quarter	\$1.40	\$0.40



**GENAISSANCE
PHARMACEUTICALS**

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