APPLERA CORP
Form 10-K
September 09, 2004

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

FORM 10-K

Annual Report Pursuant to Section 13 Or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended June 30, 2004

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 Number 1-4389

Applera Corporation
(Exact name of registrant as specified in its charter)

DELAWARE	**06-1534213**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
301 Merritt 7, Norwalk, Connecticut	**06851-1070**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: 203-840-2000

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

Title of Class	**Name of Each Exchange on Which Registered**
Applera Corporation-Applied Biosystems Group Common Stock (par value $0.01 per share)	**New York Stock Exchange Pacific Exchange**
Rights to Purchase Series A Participating Junior Preferred Stock (par value $0.01 per share)	**New York Stock Exchange Pacific Exchange**
Applera Corporation-Celera Genomics Group Common Stock (par value $0.01 per share)	**New York Stock Exchange Pacific Exchange**
Rights to Purchase Series B Participating Junior Preferred Stock (par value $0.01 per share)	**New York Stock Exchange Pacific Exchange**

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

Title of Class
Class G Warrants

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 this Form 10-K.

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

As of December 31, 2003, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of Applera Corporation-Applied Biosystems Group Common Stock (based upon the average of the high and low price) held by non-affiliates was $4,273,700,698, and the aggregate market value of Applera Corporation-Celera Genomics Group Common Stock (based upon the average of the high and low price) held by non-affiliates was $1,021,199,248. As of September 3, 2004, 195,710,205 shares of Applera Corporation-Applied Biosystems Group Common Stock and 73,031,206 shares of Applera Corporation-Celera Genomics Group Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Annual Report to Stockholders for Fiscal Year ended June 30, 2004 - Parts I, II, and IV.

Proxy Statement for 2004 Annual Meeting of Stockholders - Part III.

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EXHIBITS, INCLUDING CERTIFICATIONS

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PART I

Item 1. Business

Company Overview

Business Segments

Applera Corporation conducts business through three business segments, which are described below. Throughout this report, terms such as Applera, we, us, or our may be used to refer to Applera Corporation.

Applied Biosystems Group. Our Applied Biosystems Group, which we refer to as Applied Biosystems throughout this report, serves the life science industry and research community by developing and marketing instrument-based systems, consumables, software, and services. Its customers use these tools to analyze nucleic acids (DNA and RNA), small molecules, and proteins to make scientific discoveries, develop new pharmaceuticals, and conduct standardized testing. A description of this business segment and developments during our 2004 fiscal year is set forth below in this Item 1 under the heading Applied Biosystems Group Business.

Celera Genomics Group. Our Celera Genomics Group, which we refer to as Celera Genomics throughout this report, is engaged principally in the discovery and development of targeted therapeutics for cancer, autoimmune, and inflammatory diseases. Celera Genomics is leveraging its proteomic, bioinformatic, and genomic capabilities to identify and validate drug targets, and to discover and develop small molecule therapeutics. It is also seeking to advance therapeutic antibody and selected small molecule drug programs in collaboration with global technology and market leaders. A description of this business segment and developments during our 2004 fiscal year is set forth below in this Item 1 under the heading Celera Genomics Group Business.

Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics. Celera Diagnostics, a joint venture formed by Applied Biosystems and Celera Genomics in April 2001, is focused on the discovery, development, and commercialization of diagnostic products. A description of this business segment and developments during our 2004 fiscal year is set forth below in this Item 1 under the heading Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics.

Information about the risk factors associated with our business segments is set forth below in Item 5 of Part II of this report under the headings Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Forward Looking Statements and Risk Factors.

We maintain a corporate staff to provide accounting, tax, treasury, legal, information technology, human resources, and other internal services for Applied Biosystems, Celera Genomics, and Celera Diagnostics.

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Corporate History and Structure; Two Classes of Stock

Applera was incorporated in 1998 under the laws of the State of Delaware. Applera is the successor to The Perkin-Elmer Corporation, a corporation originally formed in 1939, as a result of a recapitalization completed in May 1999. As part of the 1999 recapitalization, Applera established the following two classes of common stock that were intended to reflect separately the relative performance of the businesses of Applied Biosystems and Celera Genomics, which are business units of Applera and are not separate legal entities:

Applera Corporation-Applied Biosystems Group Common Stock, which we refer to in this report as Applera-Applied Biosystems stock; and

Applera Corporation-Celera Genomics Group Common Stock, which we refer to in this report as Applera-Celera stock.

More information about Applera-Applied Biosystems stock and Applera-Celera stock is set forth below in Item 5 of Part II of this report under the headings Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Information about our Common Stock and its Holders. Also, information about the risk factors associated with our capital structure and our two classes of stock is set forth below in Item 5 of Part II of this report under the headings Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Forward Looking Statements and Risk Factors.

Available Information

Websites. We maintain Internet websites for Applera, Applied Biosystems, Celera Genomics, and Celera Diagnostics. All interested persons can access the following information on these websites, free of charge:

our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission;

Section 16 insider transaction reports, which include Forms 3, 4, and 5, filed by our officers and directors with the SEC; and

information relating to our corporate governance, including: our Corporate Governance Guidelines; our Code of Business Conduct and Ethics, which is applicable to our officers, directors, and employees; the charters for the Audit/Finance Committee, the Management Resources Committee, and the Nominating/Corporate Governance Committee of our Board of Directors; information on how to communicate with our Board of Directors, including our non-management directors; and information on how to report valid complaints to the Company regarding accounting and related matters.

We make our SEC reports and the insider transaction reports available on our websites as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

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The following table indicates how to access the documents described above on our websites:

	Website Address	SEC Filings	Insider Transaction Reports	Corporate Governance Information
Applera	www.applera.com	Click on the link to SEC Filings in the Investors & Media section of the website, and then click again on the link to SEC Filings	Click on the link to SEC Filings in the Investors & Media section of the website, and then click again on the link to SEC Insider Filings	Click on the link to Corporate Governance in the Corporate section of the website
Applied Biosystems	www.appliedbiosystems.com	Click on the link to SEC Filings in the Investors section of the website, and then click again on the link to SEC Filings	Click on the link to SEC Filings in the Investors section of the website, and then click again on the link to SEC Insider Filings	Click on the link to Corporate Governance in the Investors section of the website
Celera Genomics	www.celera.com	Click on the link to SEC Filings in the Investors & Media section of the website, and then click again on the link to SEC Filings	Click on the link to SEC Filings in the Investors & Media section of the website, and then click again on the link to SEC Insider Filings	Click on the link to Corporate Governance in the Investors & Media section of the website

In addition, you can obtain copies of these materials by calling our corporate Secretary at 203-840-2000 or by making a request in writing mailed to: Attention: Secretary, Applera Corporation, 301 Merritt 7, P.O. Box 5435, Norwalk, CT 06856-5435.

Except for the documents on our websites that are expressly incorporated by reference into this report, the information contained on our websites is not incorporated by reference into this report and should not be considered to be a part of this report. This includes the websites referred to in the table above, as well as other websites that we refer to elsewhere in this report. All of these website addresses are included in this document as inactive textual references only.

Information Incorporated by Reference. The SEC allows us to incorporate by reference some information from parts of other documents filed with the SEC, including:

- our Annual Report to Stockholders for our 2004 fiscal year, which we refer to in this report as our 2004 Annual Report; and
- our Proxy Statement relating to our Annual Meeting of Stockholders to be held on October 21, 2004, which we refer to in this report as our 2004 Proxy Statement.

When we incorporate by reference, that means that we are referring you to important information in other documents that have been filed with the SEC rather than repeating that information in this report. We recommend that you refer to the information that we indicate is contained in the other documents and which is incorporated by reference into this report. The portions of our 2004 Annual Report that are incorporated by reference into this report are included as Exhibit 13 to this report.

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Scientific Background

All living organisms contain biological molecules. The most numerous are in the categories of: nucleic acids, which include DNA and RNA; proteins; carbohydrates; and lipids. Biological molecules are typically much larger and more complex than common molecules, and there is a wide diversity in the types of biological molecules present in living organisms. These characteristics make the analysis of biological molecules significantly more complex than the analysis of smaller compounds. Key advances in therapeutics have historically often come from an understanding of either proteins or DNA.

DNA molecules provide instructions that ultimately control the synthesis of proteins within a cell, a process referred to as gene expression. DNA molecules consist of chemical subunits, called nucleotides, bound in two long strands formed by a chemical backbone made up of sugar and phosphate molecules. There are four nucleotides adenine, cytosine, guanine, and thymine often abbreviated with their first letters A, C, G, and T and often referred to as bases. In a DNA molecule, the nucleotides in the two strands are bound together in pairs to form a structure that resembles a twisted ladder, which is often referred to as a double helix. The bound pairs of nucleotides, which form the rungs of the ladder, are often referred to as base pairs.

Genes are individual segments of these DNA molecules that carry the specific information necessary to construct particular proteins. Genes may contain from several dozen to tens of thousands of nucleotides. The entire collection of DNA in an organism, called the genome, may contain a wide range of nucleotides, including as few as 4 million nucleotides in the case of simple bacteria and 3.1 billion base pairs of nucleotides in the case of human beings.

RNA molecules are similar to DNA in structure and are essential for biological function through a number of biochemical activities within the human body. There are different types of RNA molecules, each of which has a different function. For example, messenger RNA, the most common form of RNA, acts as an intermediary between DNA and protein, transcribing the genetic code from DNA into protein.

Principally driven by the biotechnology revolution, and the increasing focus on DNA, researchers are developing a better understanding of DNA s role in human disease. An increased appreciation of how DNA ultimately determines the functions of living organisms has generated a worldwide effort to identify and sequence genes of many organisms, including the genes that make up the human genome. We believe the best scientific evidence to date indicates that the number of genes in the human genome that code for proteins is between 25,000 and 35,000, which is significantly less than had been previously thought. The study of genes and other genetic material of organisms is now commonly referred to as genomics.

The field of genomics research generally includes three broad categories of analysis, consisting of sequencing, genotyping, and gene expression studies:

Sequencing is performed to determine the exact order of the individual nucleotides in a DNA strand. Sequencing was used to identify the nucleotides in the entire human genome and other species. It has also been used to identify naturally occurring genetic variations in the human genome, which are referred to as single nucleotide polymorphisms or SNPs. Scientists believe that SNPs can be correlated with, for

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example, susceptibility to disease, disease prognosis, therapeutic efficacy, and therapeutic toxicity, and therefore may have diagnostic or therapeutic utility.

Genotyping is performed to determine a particular sequence variant of a gene and its particular association with an individual s DNA. Genotyping is not performed to determine the complete structure of the gene, but rather is performed to determine if the particular DNA sequence variant, typically a SNP, can be associated with, for example, susceptibility to a particular disease or response to a particular drug.

Gene expression is performed to determine whether a particular gene is expressed, or present, and in some cases at what levels, in a relevant biological material. This analysis can be used, for example, to measure and compare gene activity in various biological samples, such as samples from populations of healthy and diseased individuals, or from populations at different stages of disease development. These types of studies may be useful in the development of diagnostic tests and therapeutic treatments.

As researchers learn more about DNA and genes, they are also developing a better understanding of the role of proteins in human disease through efforts in the field of proteomics, the study of proteins expressed, or coded, by genes. Proteins are the products of genes and, along with gene expression and modification, are believed to be key drivers and mediators of cellular function and biological system activity. The understanding and treatment of disease today involves the study of genes and the proteins they code for, and frequently involves the measurement of a drug s ability to bind to specific proteins in the body.

Although DNA contains the code for proteins, scientists have discovered that the body may modify proteins after they have been made in cells. These modifications, referred to as post-translational modifications, can alter a protein s function, leading to changes in the biological reactions that take place in cells, which researchers refer to as biological pathways. These post-translational modifications complicate the study of proteins, because scientists studying proteins and seeking to understand their role in health and disease need a more thorough characterization of proteins than simply knowing their genetic, or DNA, code.

We believe that gene and protein research will increase as companies in the pharmaceutical and biotechnology industries seek to improve their drug discovery and development efforts. We also believe that ongoing drug discovery and development efforts will increase research of cells as researchers seek to further understand how drugs work in the body.

The growth in DNA, protein, and other research has created the need for systems that facilitate the collection, organization, and analysis of the large amounts of data generated by this research. This demand has led to the development of the science of bioinformatics. The science of bioinformatics seeks to blend biology and computing to transform massive amounts of data into useful information.

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Applied Biosystems Group Business

Overview

Applied Biosystems serves the life science industry and research community by developing and marketing instrument-based systems, consumables, software, and services. Its customers use these tools to analyze nucleic acids (DNA and RNA), small molecules, and proteins to make scientific discoveries, develop new pharmaceuticals, and conduct standardized testing. Applied Biosystems products are designed to address the demand for increased automation and efficiency in pharmaceutical and biotechnology laboratories by combining the detection capabilities of analytical instruments with advances in automation and laboratory work-flow design. The markets for Applied Biosystems products span the spectrum of the life sciences industry and research community, including: basic human disease research and genetic analysis performed by universities, government agencies, and other non-profit organizations; pharmaceutical drug discovery, development, and manufacturing; human identification; agriculture; biosecurity, which refers to products needed in response to the threat of terrorism; and food and environmental testing.

Applied Biosystems expects its ongoing research and development efforts will increasingly focus on integrated science solutions, which we refer to as iScience, to expedite our customers research and commercial goals. Scientists are increasingly adopting approaches that link technology, computer science, and traditional laboratory research to enable the study of complex biological systems and disease. This trend is evidenced by a growing number of high-profile initiatives and institutions worldwide dedicated to systems biology, which refers generally to the coordinated, integrated, and interdisciplinary study of the various parts of a biological system rather than just the focused study of individual parts such as genes, proteins, or cells. Applied Biosystems believes that the increasing availability of high-quality biological data and advances in technology are transforming the study of complex biological systems, but that the overwhelming amount of available biological information creates economic and practical challenges for this study. Consequently, Applied Biosystems is seeking to develop iScience products and services that help customers more easily and cost effectively leverage recent biological information and technological advances.

During our 2004 fiscal year, Applied Biosystems engaged a leading strategy consulting firm to assist management in an in-depth review of the group s entire product portfolio. The purpose of this review is to identify opportunities for growth, increased profitability, and shareholder value creation. The first two phases of the project, which have been completed, included: a rigorous fact-based analysis of Applied Biosystems current product portfolio; an evaluation of research and development investments in an attempt to achieve optimum alignment with future growth opportunities; and an examination of Applied Biosystems business processes with a goal to improving operational efficiency and productivity. A third phase of this review is ongoing, during which Applied Biosystems is seeking to identify and analyze additional internal and external growth opportunities. As part of this business review, Applied Biosystems has been evaluating portfolio decisions, and this process has led to changes in, and may in the future result in further changes in, Applied Biosystems product and business mix.

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In July 2004, subsequent to the end of our 2004 fiscal year, Applied Biosystems announced a new organization structure which resulted from the strategic review described in the preceding paragraph. The new structure, which is expected to be substantially phased in by the end of September 2004, will create the following four business divisions, each led by a division President: Molecular Biology; Proteomics and Small Molecules; Applied Markets; and Service. Applied Biosystems intends to create integrated and fully-functioning divisions with the resources necessary to execute their business plans, including strategic planning, research and development, marketing, and sales professionals. The four new business divisions will be supported by several cross divisional functions, including units focused on Applied Biosystems strategic planning and business development, investigation of advanced technologies, and incubation of new businesses in new or underserved markets. Also, these operating activities will continue to be supported by a shared service organization responsible for functions such as human resources, finance, communications, legal, and intellectual property.

Also, in August 2004, subsequent to the end of our 2004 fiscal year, Applied Biosystems announced the retirement of Michael W. Hunkapiller, Ph.D., Senior Vice President and President, Applied Biosystems Group. At the same time, Applied Biosystems announced the promotion of Catherine M. Burzik, formerly a Vice President of Applera and Executive Vice President and Chief Operating Officer of Applied Biosystems, to the position left by Dr. Hunkapiller.

For information on revenues from instruments and consumables for our 2002, 2003 and 2004 fiscal years, refer to pages 31 and 33 of Management s Discussion and Analysis in our 2004 Annual Report, which pages are incorporated herein by reference.

Products for the Genomics Market

Customers in the genomics market use systems for the analysis of nucleic acids for: basic research; pharmaceutical and diagnostic discovery and development; biosecurity; food and environmental testing; analysis of infectious diseases; and human identification and forensic analysis. Applied Biosystems has developed technologies and products to support key applications in genomics research such as sequencing, genotyping, and gene expression studies. Applied Biosystems products for the genomics market are described in the following paragraphs.

PCR Instruments, including Thermal Cyclers and Real-Time PCR Systems, and Related Consumables. Polymerase chain reaction, commonly referred to as PCR, is a process in which a short strand of DNA is copied multiple times, or amplified, so that it can be more readily detected and analyzed. Applied Biosystems PCR product line includes amplification instruments, known as thermal cyclers, several combination thermal cyclers and PCR detection systems, and reagents and software necessary for the PCR amplification and detection process.

The Dual 384-Well GeneAmp® PCR System 9700 thermal cycler is the highest capacity thermal cycler offered by Applied Biosystems. This instrument supports all key applications in genetic analysis and fills a significant market need for laboratories conducting high-volume genomics research. This instrument is referred to as a dual 384-well instrument because it can simultaneously amplify samples in two plastic trays, referred to by researchers as microtiter plates, each having wells to hold 384 samples. Applied Biosystems also offers 60- and 96-well thermal cyclers and a dual 96-well thermal cycler. Applied Biosystems PCR product line also includes reagents for high-fidelity, or high-accuracy, amplification of long DNA segments.

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These are useful in the determination of haplotypes, which are correlated patterns of inherited DNA mutations. Scientists are just beginning to understand haplotypes and use them in complex disease-gene association studies.

Applied Biosystems real-time PCR systems product line, which it previously referred to as its Sequence Detection Systems product line, includes its ABI PRISM 6100 Nucleic Acid PrepStation for sample preparation and its real-time PCR instruments for analysis. The ABI PRISM 6100 Nucleic Acid PrepStation extracts DNA and/or RNA from whole cells, blood, and other samples. This DNA or RNA, largely separated from the other molecules found in cells, can then be analyzed in instruments largely without interference from those other molecules, such as proteins. The ABI PRISM 6100 Nucleic Acid PrepStation was designed to decrease the labor and cost involved in preparing DNA and RNA for analysis by automating some aspects of this key phase in the sample preparation process. Applied Biosystems had previously marketed the ABI PRISM 6700 Automated Nucleic Acid Workstation, which fully automated several key steps in sample preparation, including the extraction process described above. However, Applied Biosystems discontinued this higher-priced instrument as of the end of our 2004 fiscal year, though it continues to provide servicing and support for this instrument.

Applied Biosystems offers four real-time PCR instrument systems for the detection and quantitation of nucleic acids: The ABI PRISM® 7900HT Sequence Detection System, the ABI PRISM 7000 Sequence Detection System, the Applied Biosystems 7300 Real-Time PCR System, and the Applied Biosystems 7500 Real-Time PCR System. The model 7900HT system is a flexible, automated analyzer that can be used with 96-well and 384-well plates as well as Applied Biosystems TaqMan® Low Density Array, which is described below. In its highest throughput configuration, using 384-well plates and robotics, this system can be used for large-scale gene expression and genotyping studies. Applied Biosystems began marketing the model 7300 and 7500 systems during our 2004 fiscal year. These instruments are designed to provide smaller laboratories with a more economical, yet versatile system for a broad range of applications, with the model 7500 system offering additional features and capabilities in comparison to the model 7300 system. These are next generation systems that have been designed with technological improvements that enhance performance and flexibility, though they are less automated than the model 7900HT system and do not have the same throughput capability because they use only 96-well plates. The model 7000 system is an older instrument that was also designed for the needs of smaller laboratories, and was the precursor to the model 7300 and 7500 systems. Limited demand for this product is expected to continue because some research and applied markets applications require the use of a system such as the model 7000 system that has been previously validated, or demonstrated acceptable, by users for those applications.

All of the real-time PCR Systems are modified versions of Applied Biosystems thermal cyclers, which are described above, and use TaqMan® chemistry, a unique PCR technology designed by the Roche Group and developed by Applied Biosystems. TaqMan chemistry can be used both for measurement of gene expression and for genotyping. TaqMan chemistry detects the product of PCR amplification and quantifies the initial sample during the amplification process. This technique is referred to as quantitative real-time PCR. The real-time PCR systems analyze a sample by measuring fluorescence resulting from the reaction of the TaqMan chemistry and the sample. This product line has been widely accepted in the pharmaceutical discovery research market. Applied Biosystems TaqMan Gene Expression Assays and SNP Genotyping Assays are TaqMan chemistry-based assays designed for use on Applied Biosystems real-time PCR systems. These products are described below in Item 1 of this report

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under the headings Applied Biosystems Group Business Products for the Genomics Market Genomic Assays.

Applied Biosystems offers a proprietary TaqMan Low Density Array (which it formerly referred to as its Micro Fluidic Card system), which was jointly developed with 3M Company, and a modified version of its model 7900HT system to support the Low Density Arrays for gene expression analysis. The Low Density Arrays are consumable laminated plastic sheets containing 384 microscopic fluid channels and wells. They are designed for use instead of microtiter plates, which are used in many types of laboratory analyses, including gene expression or genotyping studies on Applied Biosystems instruments. The microscopic fluid channel design of the Low Density Arrays enables researchers to automatically route a sample to the reaction wells rather than doing this by hand or using expensive and complex robotics as is required when using microtiter plates. Applied Biosystems is currently offering the Low Density Arrays pre-loaded with its human, mouse, and rat TaqMan Gene Expression Assays, which are described below in Item 1 of this report under the headings Applied Biosystems Group Business Products for the Genomics Market Genomic Assays. Using an on-line ordering system, customers can customize the cards by selecting the assays that are pre-loaded onto the Low Density Arrays.

Genetic Analysis Instruments; Genotyping and Resequencing Systems. Applied Biosystems genetic analysis instruments, referred to as DNA or genetic analyzers, can be used to perform both DNA sequencing and fragment analysis. DNA sequencing is used to determine the exact order of nucleotides in a strand of DNA. DNA fragment analysis is used to determine the size, quantity, or pattern of DNA in a strand of DNA. DNA sequencing instruments have been used extensively to obtain the DNA sequence of the human genome and the genomes of other species and to identify SNPs and other genetic mutations.

Applied Biosystems genetic analysis instruments use electrophoresis to analyze molecules. During electrophoresis, the molecules being analyzed are placed in a separation medium, usually a gel, and then subjected to an electric charge. The molecules will pass through the gel at different speeds because the molecules have different lengths and electrical charges. Typically, the molecules being analyzed are labeled, or chemically linked, with fluorescent tags before being subjected to the electrophoresis, with each of the four different nucleotides A, C, G, and T being labeled with a different color tag. During electrophoresis, the genetic analysis instrument can analyze the molecules by using an optical device that can read the fluorescent tags. Applied Biosystems offers several sequencing chemistries optimized for various customer requirements. Samples prepared using these chemistries are then analyzed on Applied Biosystems genetic analysis instruments.

All of Applied Biosystems genetic analysis instruments now use capillaries, which are tubes through which a DNA sample moves during electrophoresis. Capillary systems have higher throughput and greater automation than those based on slab-gels, an older and less efficient technology. Applied Biosystems offers the following genetic analysis instruments:

Instrument	**Description**
Applied Biosystems 3730*xl* DNA Analyzer	96 capillary sequencer
Applied Biosystems 3730 DNA Analyzer	48 capillary sequencer
ABI PRISM® 3100 Genetic Analyzer	16 capillary sequencer
ABI PRISM® 3100-*Avan*t Genetic Analyzer	4 capillary sequencer
ABI PRISM® 310 Genetic Analyzer	1 capillary sequencer

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Applied Biosystems provides servicing and customer support for these instruments.

The model 3730*xl* DNA Analyzer has superseded the 96 capillary model 3700 DNA Analyzer, which is no longer offered for sale by Applied Biosystems although Applied Biosystems continues to provide servicing and support for this instrument. At the time of its introduction in 1999, the model 3700 instrument represented a significant advance in DNA sequencing technology because it could perform high-throughput analysis of samples in unattended operation. The model 3700 instrument was the principal instrument used by Celera Genomics for sequencing human and other genomes, and we believe the model 3700 instrument is also the principal instrument used by the Human Genome Project for its sequencing projects. The model 3730*xl* instrument offers significant advances in data quality, throughput, and cost effectiveness over the model 3700 instrument. Because of these advances, the model 3730*xl* instrument is able to read longer DNA fragments than its predecessor. For a given sequencing project, this means that customers using the model 3730*xl* instrument will need to process fewer samples, lowering their preparation costs. Also, by incorporating a more sensitive optical design, the model 3730*xl* instrument is able to complete the same analysis with lower reagent consumption per sample. The 48-capillary model 3730 instrument, which incorporates the same technological advances as the model 3730*xl* instrument, can be upgraded to become a 96-capillary model 3730*xl* instrument.

The 16-capillary model 3100 Genetic Analyzer was designed for use by academic programs and commercial laboratories. It was the technological precursor of the model 3730 DNA Analyzer and incorporates many of the same features, though it has lower throughput and is less expensive. The 4-capillary model 3100-*Avant* Genetic Analyzer is a reduced capacity instrument derived from the model 3100 Genetic Analyzer and has a lower cost than the model 3100 instrument. A model 3100-*Avant* Genetic Analyzer can be upgraded to a model 3100 Genetic Analyzer. Applied Biosystems has discontinued sales of its ABI PRISM 377 DNA Sequencer, the last of its instruments to use slab-gel technology, although Applied Biosystems continues to provide servicing and support for this instrument.

In January 2004, Applied Biosystems began marketing the SNPlex Genotyping System. The SNPlex system uses multiplexing, a scientific term that refers to multiple reactions in a single tube or well, to rapidly identify large numbers of target SNPs in a single biological sample. Using this system, customers can perform studies based on Applied Biosystems proprietary SNP reference library or their own customized set of reference SNPs. The system consists of reagents and software for use on the Applied Biosystems 3730 and 3730*xl* DNA Analyzers. The high-throughput genotyping capabilities of this new system complement the PCR-based genotyping that can be performed by the Applied Biosystems real-time PCR instrument systems. Applied Biosystems expects that researchers seeking to perform genotyping will choose between these alternative technologies based on a variety of factors, including the type of studies they are performing, the scientific requirements of these studies, their access to the needed instrumentation, and their budgets.

In February 2004, Applied Biosystems began marketing the VariantSEQr Reseqencing System. This system is a comprehensive solution for researchers seeking to perform resequencing, which refers to a method by which the DNA sequence information of one or multiple DNA samples is compared to a known reference sequence to determine whether any genetic variations are present. Scientists may use this information to, for example, better understand the causes and prevention of disease, facilitate the development of better and more

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targeted therapies and diagnostics, and understand individual response to treatment. Applied Biosystems believes that the VariantSEQr system will enable scientists to perform resequencing studies that were previously impractical and too expensive to perform because of the amount of time, labor, and expertise needed for experiment setup. The VarianSEQr system integrates reagents and software for use on the Applied Biosystems 3730 and 3730*xl* DNA Analyzers and 3100 and 3100-*Avant* Genetic Analyzers. Using this system, researchers can perform resequencing of more than four thousand human genes. Applied Biosystems intends to introduce additional resequencing sets for this system that will enable the resequencing of more human genes as well as DNA of non-human genes such as pathogens.

Genomic Assays. Our genomic assays are chemical tests used to measure a DNA or RNA target. A genomic assay combines a set of pre-selected oligonucleotides or oligos, which are synthetic single-stranded pieces of DNA, with other analytical reagents that allow a researcher to measure differences between samples of genetic material. For example, a gene expression assay is a chemical test to measure how much RNA is being produced from a specific gene in the cells of a tissue sample. A genotyping assay is a chemical test to measure the presence or absence of a specific genetic sequence variation or mutation among DNA samples from different populations that can be used to correlate genetic traits with physical traits such as disease susceptibility or drug response. Applied Biosystems genomic assays include several products and services for both gene expression and genotyping, which are described in the following table.

Gene Expression Assays	**Description**
TaqMan Gene® Expression Assays	Ready-made gene expression assays that can be ordered from Applied Biosystems inventory
TaqMan® Pre-Designed Gene Expression Assays	Pre-designed gene expression assays that can be made to order
Custom TaqMan® Gene Expression Assays	Service for the manufacture of custom TaqMan chemistry-based gene expression assays based on targets supplied by researchers

SNP Genotyping Assays	**Description**
TaqMan® SNP Genotyping Assays	Ready-made SNP genotyping assays that can be ordered from Applied Biosystems inventory
TaqMan® Pre-Designed SNP Genotyping Assays	Pre-designed SNP genotyping assays that can be made to order
TaqMan® Coding SNP Genotyping Assays	Ready-made SNP genotyping assays within protein coding regions of genes that can be ordered from Applied Biosystems inventory
Custom TaqMan® SNP Genotyping Assays	Service for the manufacture of custom TaqMan chemistry-based SNP genotyping assays based on targets supplied by researchers

Since the initial launch of its genomic assays in our 2002 fiscal year, Applied Biosystems has continued to increase the number of assays available and currently offers a large library of ready-made and pre-designed SNP genotyping and gene expression assays. This library includes over 1.5 million human SNP genotyping assays, and over 300,000 gene expression assays including assays for the human, mouse, and rat genomes. The ability to study the mouse and rat genomes is important to researchers involved in, for example, therapeutic research and development because mice and rats have genes that are believed to correspond to human genes and the results of disease research or safety, toxicology, or other studies on mice or rats may therefore be correlated to humans with corresponding genetic characteristics. Applied Biosystems originally launched its genomic assay product and service lines under the names Assays-on-Demand, which included its ready-made assays, and Assays-by-Design, which

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included its service for the manufacture of custom assays. During our 2004 fiscal year, Applied Biosystems renamed these product lines and expanded them to include the pre-designed assays described above.

Researchers traditionally have used home brew assays, which are assays that researchers both design and prepare themselves in their laboratories, a process that is relatively time consuming and expensive. Applied Biosystems believes that its ready-made and pre-designed genomic assays offer significant advantages to researchers compared with home brew assay design. These advantages include:

facilitation of experiments with many genes in parallel;

substantial reduction in experiment setup time;

decreased assay cost; and

creation of a set of standard and validated assays that enable comparisons of data between laboratories.

Applied Biosystems SNP genotyping and gene expression assays are designed to be used with Applied Biosystems real-time PCR systems.

Microarrays. Applied Biosystems offers the Applied Biosystems Expression Array System for gene expression analysis. This system combines microarray technology and a proprietary chemiluminescence technology and was designed to detect the expression of a greater number of genes, with higher sensitivity and specificity, while using less biological sample, than existing commercially-available microarray technologies. This system is highly sensitive because it can detect low levels of gene expression, and highly specific because of its accuracy in identifying the presence of expressed genes without falsely reading the presence of expression from other genes. Applied Biosystems commenced sales of this product in April 2004.

Microarray technology involves the miniaturization of reactions on a single consumable product to enable a large number of simultaneous reactions or analyses. Applied Biosystems microarrays are small, porous nylon plates that can be used to analyze in parallel the expression of approximately 28,000 human genes in a sample. The microarrays are used in combination with the 1700 Chemiluminescent Microarray Analyzer, an instrument that measures gene expression by detecting chemiluminescence, which is the conversion of chemical energy stored within a molecule into light. DNA probes, which are single-stranded pieces of DNA, are chemically attached to the microarray and designed to cause a chemiluminescent reaction in the presence of expression targets. The DNA probes used for this application are approximately 60 bases long. Applied Biosystems believes the use of chemiluminescence rather than fluorescence, and the use of longer probes, results in higher sensitivity and specificity compared to existing commercially-available microarray systems.

Applied Biosystems designed this system to complement the gene expression capabilities of its TaqMan chemistry-based real-time PCR System products. Researchers performing whole genome expression studies using the Expression Array System can validate their results and perform further analysis on Applied Biosystems real-time PCR systems.

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In May 2004, Applied Biosystems commenced commercial sales of whole genome expression arrays for the mouse genome, and plans to introduce a whole genome expression array for the rat genome in the future. The ability to study mouse and rat genomes is important to researchers involved in therapeutic research and development because mice and rats have genes that are believed to correspond to human genes and the results of disease research or safety, toxicology, or other studies on mice or rats may therefore be correlated to humans with corresponding genetic characteristics.

DNA Synthesis. DNA synthesizers produce synthetic single-stranded pieces of DNA for genetic analysis. These molecules, referred to as oligonucleotides or oligos, are an essential reagent for PCR and DNA sequencing and are also used in drug discovery applications. DNA synthesis is used both by companies performing high-throughput synthesis as a service as well as individual laboratories that synthesize DNA for their own use. Applied Biosystems offers several models of synthesizers and supporting reagents for the needs of its different customers. Applied Biosystems also provides custom synthesis, in which oligonucleotides are made to order and shipped to customers.

PNA. Applied Biosystems has a license, which is exclusive for some applications, to manufacture and sell peptide nucleic acid within various markets including the molecular biology research market. Peptide nucleic acid, which is often referred to as PNA, resembles DNA in its chemical structure except that it has a neutral peptide-like backbone, whereas DNA has a negatively charged sugar phosphate backbone. The unique chemical structure of PNA enhances its affinity and specificity as a DNA or RNA probe. Probes are used in various types of analysis, and are used to search for DNA and RNA sequences in a sample by binding to those sequences if they are present. PNA may be used in many areas, including basic research, pharmaceutical discovery, diagnostic development, and food and environmental testing. During our 2002 fiscal year, Applied Biosystems acquired additional rights to PNA technology, particularly exclusive rights in the field of diagnostics, through its acquisition of Boston Probes, Inc. and a party related to Boston Probes. During the fourth quarter of our 2004 fiscal year, Applied Biosystems recorded pre-tax charges of $14.9 million relating to Boston Probes. These charges are described in Note 2 to our fiscal 2004 Consolidated Financial Statements, which are incorporated by reference into Item 8 of this report.

Products for the Proteomics Market

Genes code for proteins in biological organisms, and proteins are the key biological molecules that function in all aspects of living things such as growth, development, and reproduction. The body may also modify proteins after they are made in cells, and such modifications, referred to as post-translation modifications, often alter the function of the modified protein. These post-translational modifications are not encoded in the protein s genetic, or DNA, code.

Differences in the types or amounts of specific proteins in biological systems are thought to be the primary differences between healthy and diseased systems or organs. A majority of drugs to treat human disease bind to and affect proteins. Proteins are large biological molecules made up of peptides, and peptides are made up of amino acids chemically linked together in long chains and frequently modified by the addition of chemical units such as sugar chains or phosphate groups. Customers in the proteomics research market need systems for the analysis of proteins and peptides for the purpose of discovery of drug targets, protein therapeutics, and diagnostics. Applied Biosystems has developed products for the identification, characterization,

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and measurement of expression of proteins and peptides. Applied Biosystems products for the proteomics market are described in the following paragraphs.

Mass Spectrometry. Mass spectrometry has become very useful for the analysis of large molecules of biological importance such as proteins. Analysis of proteins and other molecules by mass spectrometry involves the very accurate measurement of the mass, or size, of components in a sample, such as the measurement of the multiple different peptides that make up a defective protein. The technique involves the measurement of these molecules in instruments using very high vacuum and sensitive electronics capable of measuring extremely fine differences in very small quantities of complex samples with multiple components. The technique of mass spectrometry requires that the following key elements be incorporated into the instrument:

A unique sample preparation process called ionization to charge the molecules for analysis. Applied Biosystems sells instruments with ionization by either a laser based system called MALDI, which refers to matrix assisted laser desorption ionization, or a high voltage electric system called ESI, which refers to electrospray ionization.

Mass analysis and detection, which involves the separation and electronic measurement of the mass of molecules and the measurement of the relative amounts present. Applied Biosystems has a variety of mass analysis technologies which separate and measure the mass of molecules in a sample. These include TOF, which refers to time of flight, which measures mass based on flight time in an electric field under vacuum; and quadrupole or quad, and linear ion trap, both of which measure mass using radio frequencies and electric charges though using related but different technologies.

Mass spectrometry products are often referred to or named based on their sample preparation and mass analysis technologies. For example, a MALDI TOF instrument is an instrument that uses MALDI to charge molecules for analysis and TOF for mass analysis. Also, mass spectrometry instruments are often referred to or named based on whether they are connected to liquid chromatography separation devices, which are used for sample preparation prior to analysis using mass spectrometry. For example, an LC/MS system is a liquid chromatography device connected directly to a mass spectrometry instrument, and an LC/MS/MS system is a liquid chromatography device coupled with tandem mass spectrometry instruments. Tandem mass spectrometry enables a more detailed and accurate analysis of the components of the molecules being studied.

The market for mass spectrometry is served by a wide range of instrument types based on a variety of technologies for both ionization and mass analysis and combined together in different combinations in different instruments. The different instrument types, technologies, and combinations result in differing performance characteristics and price levels, and the suitability of any particular system for any researcher or research laboratory will depend on the nature of the work being performed and the capital budget of the researcher or research laboratory.

Applied Biosystems and Applied Biosystems/MDS SCIEX Instruments, a joint venture between Applied Biosystems and MDS Inc. of Canada, supply a broad family of mass spectrometry products for the proteomics market that involve different combinations of these

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technologies. Customers select from this range of product types based on their budgets, workflows, sample types, preferences, and experience. Under the terms of the joint venture agreement with MDS Inc., Applied Biosystems has the exclusive worldwide distribution rights to the LC/MS systems manufactured for the joint venture by the MDS SCIEX Division of MDS Inc. for the analytical instruments market.

The following table summarizes the mass spectrometry instruments offered by Applied Biosystems, including those manufactured through its MDS SCIEX Instruments joint venture, for the proteomics market:

Instrument Name	Ionization	Mass Analyzer
Voyager -DE PRO Biospectrometry Workstation	MALDI	TOF
Voyager -DE STR Biospectrometry Workstation	MALDI	TOF
4700 Proteomics Discovery System	MALDI	TOF/TOF Optics
QSTAR® XL Hybrid LC/MS/MS System	ESI or MALDI	Hybrid quad/TOF (often referred to as a Qq-TOF)
Q TRAP® LC/MS/MS System	ESI	Hybrid quad/linear ion trap
4000 Q TRAP® LC/MS/MS System	ESI or MALDI	Hybrid quad/linear ion trap

The 4700 Proteomics Discovery System and the 4000 Q TRAP LC/MS/MS System, both introduced in our 2003 fiscal year, are the most recent additions to this product line. The 4700 Proteomics Discovery System was designed to address the needs of proteomic researchers for increased speed and throughput as well as enhanced data quality and molecular information. The 4700 Proteomics Discovery System incorporates a high speed MALDI system with a tandem TOF mass analyzer. Applied Biosystems/MDS SCIEX Instruments introduced the 4000 Q TRAP LC/MS/MS System to complement the Q TRAP system. The 4000 Q TRAP system is based on the same linear ion trap technology introduced with the Q TRAP system but the 4000 Q TRAP system, a higher-priced instrument, has enhanced qualitative and quantitative analysis capabilities. Applied Biosystems believes these enhancements will enable researchers to combine experiments in a single, automated system that previously required multiple mass spectrometry instruments or were not practical to perform at all. This instrument became commercially available during our 2003 fiscal year and Applied Biosystems/MDS SCIEX Instruments achieved full production capacity in January 2004.

The 4700 Proteomics system, QSTAR system, Q TRAP system, and 4000 Q TRAP system all incorporate mass spectrometry instrumentation with an online link to relevant biological information available by subscription from Applied Biosystems, including annotated protein and genome information, and bioinformatics analysis tools. Applied Biosystems believes that these system enhancements, part of its iScience strategy, will facilitate researchers efforts to characterize proteins and their functions in biological systems, including the human body.

In September 2004, subsequent to the end of our 2004 fiscal year, Applied Biosystems announced the signing of a definitive agreement with MDS Inc. to expand the scope of their Applied Biosystems/MDS SCIEX Instruments joint venture. Under the terms of the agreement, MDS has agreed to pay U.S. $40 million for a 50 percent interest in intellectual property assets related to current Applied Biosystems MALDI TOF mass spectrometry systems and next-generation products under development, together with a 100 percent interest in some MALDI TOF product-related manufacturing and research and development assets. The parties will each contribute the MALDI TOF and related intellectual property to the joint venture. Applied Biosystems, as part of its responsibilities to the joint venture, will continue to market, sell,

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service, support, and provide research support for MALDI TOF products. Following a transition period, MDS Inc., through its MDS Sciex Division, as part of its responsibilities to the joint venture, will assume primary research and development as well as full manufacturing responsibility for MALDI TOF product lines. The existing products covered by this agreement include the Voyager instruments and the 4700 Proteomics Discovery System referred to in the table above. The other products referred to in the table are already included within the joint venture. The transaction is subject to customary closing conditions, including approval by regulatory authorities in the U.S. and Canada, and is expected to close in or before the fourth calendar quarter of 2004.

In addition to the range of mass spectrometry instruments and software used to operate those instruments, Applied Biosystems has developed and commercialized reagents for quantifying, or measuring, levels of molecules in one or more samples, including reagents using ICAT® reagent technology created by Dr. Ruedi Aebersold and others while at the University of Washington. The ICAT chemistry tags or affixes a chemical marker to a peptide containing a specific type of amino acid known as cysteine. This process, when used with various mass spectrometry systems, enables the quantitation and identification of proteins in experiments that compare normal and diseased cells or samples. In our 2004 fiscal year, Applied Biosystems expanded its family of quantitiation chemistries for molecular identification with the development and commercialization of iTRAQ™ reagents. Using the iTRAQ™ reagents, researchers can affix chemical markers to all types of peptides within a protein-rich mixture, enabling the quantitation of a greater number of proteins, including the ability to detect post-translational modifications, and enabling the comparison of expression patterns within up to four samples in the same experiment. Applied Biosystems believes these new reagents complement the ICAT reagents because they enable experimentation that in many cases cannot be accomplished with the ICAT reagents. The ICAT and iTRAQ™ reagents offer laboratories a way of running protein experiments using mass spectrometry and are the foundation of an expanding family of Applied Biosystems consumables, software, and systems for proteomics.

Biochromatography. Biochromatography is an important step in both research applications and manufacturing of biopharmaceuticals, which refers to protein-based pharmaceutical products. Researchers studying complex protein samples through mass spectrometry must first prepare these samples and separate them into the components to be analyzed. A common and important technique for the separation, and in some cases purification, of biological molecules is generally referred to as biochromatography, a process by which molecules are separated according to one or more of their physical properties such as their size, shape, charge, or affinity to other molecules.

Applied Biosystems biochromatography media products are used in liquid chromatography. Liquid chromatography is a process that separates molecules by passing them, in a liquid, across a stationary or solid medium such as chemically modified plastic beads specially designed for this process. Separation occurs because different molecules, which have different affinities to the beads, will migrate, or pass, across the beads at different rates.

Applied Biosystems biochromatography media products such as its POROS® beads are used in the proteomics discovery process and in the development and manufacturing of biopharmaceuticals. Applied Biosystems believes its biochromatography products offer productivity advantages, enabled by high speed separation combined with high capacity and resolution, over competitive product offerings.

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*Protein Sequencing and Synthesis.*Proteins are large biological molecules and are made of peptides, and peptides are made of amino acids chemically linked together in long chains. Protein sequencers provide information about the sequence of amino acids that make up a given protein by chemically disassembling the protein and analyzing the amino acids. The Procise® Protein Sequencing system uses a protein sequencing chemistry known as Edman chemistry to sequence a peptide, one amino acid at a time, and in turn to identify or characterize the protein that contains the peptide.

Synthetically produced peptides are used in understanding antibody reactions and as potential drugs or drug analogs. The Applied Biosystems 433A Peptide Synthesis system is designed for the quality synthesis of peptides, peptide analogs, and small proteins. Applied Biosystems also manufactures and sells proprietary synthesis reagents and chemicals for use with this and other products.

Products for the Small Molecule Analysis Market

Applied Biosystems has a number of mass spectrometry products that life science researchers use to analyze small molecules. Small molecules studied in life science research are typically smaller than peptides and include, for example:

some drugs;

metabolites, the compounds resulting from the body s acting upon a drug, and present in bodily fluids such as blood or urine;

other small biological molecules found naturally in the human body such as hormones, which affect physiological activity by sending signals to cells and organs, and cholesterol, which the body uses, for example, to build cells and produce hormones; and

various trace contaminants in food, beverage, or environmental applications.

Mass spectrometry instruments are especially important for pharmaceutical researchers studying pharmacokinetics, the measurement of the bodily absorption, distribution, metabolism, and excretion, or elimination, of drugs. The U.S. Food and Drug Administration and other regulatory agencies require pharmacokinetic information for the approval of drugs. This application requires instruments which have a high resolution, or the ability to distinguish among different molecules with similar masses, and high sensitivity, or the ability to identify very small quantities of molecules, because the amounts of the drugs and their metabolites are very low and the mixtures are very complex. Researchers can perform the required pharmacokinetic analysis with LC/MS/MS systems that have been developed and refined by Applied Biosystems/MDS SCIEX Instruments.

Mass spectrometry instruments are growing in importance in food, beverage, and environmental applications. Various regulatory bodies worldwide monitor quality of food, beverages, and water. For these applications, we believe that speed of data acquisition, increased sensitivity, and high resolution together with ease of use are critical to satisfying customer needs.

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Applied Biosystems/MDS SCIEX Instruments offers a broad product line of mass spectrometry instruments for small molecule and pharmacokinetics researchers:

Instrument Name	Ionization	Mass Analyzer
API 2000 LC/MS/MS System	ESI or MALDI	Triple quad
API 3000 LC/MS/MS System	ESI	Triple quad
API 4000 LC/MS/MS System	ESI	Triple quad
QSTAR® XL Hybrid LC/MS/MS System	ESI or MALDI	Hybrid quad/TOF (often referred to as a Qq-TOF)
Q TRAP® LC/MS/MS System	ESI	Hybrid quad/linear ion trap
4000 Q TRAP® LC/MS/MS System	ESI or MALDI	Hybrid quad/linear ion trap

The API product line instruments offer a range of sensitivity at varying costs, the API 4000 system being the most sensitive. This product line has been widely accepted by pharmaceutical researchers, and we believe the API 4000 system is the most sensitive triple quad mass spectrometry instrument available to this research market. The 4000 Q TRAP System has the same triple quad sensitivity but is a more versatile instrument because of its hybrid mass analyzer. The QSTAR XL Hybrid LC/MS/MS System offers higher resolution and mass accuracy, or the ability to accurately determine the mass of a molecule, than the API 2000, API 3000, API 4000, and Q TRAP systems, which is particularly useful to researchers seeking to identify unknown molecules such as metabolites. General information about mass spectrometry instruments and the technologies they incorporate, and also additional information about some of the instruments referred to in the table above, is set forth above in Item 1 of this report under the headings Applied Biosystems Group Business Products for the Proteomics Market Mass Spectrometry.

In our 2004 fiscal year, the Applied Biosystems/MDS SCIEX Instruments joint venture announced a novel Tissue Imaging technology for the QSTAR XL Hybrid LC/MS/MS System that allows researchers to generate precise 2-dimensional and 3-dimensional images of low molecular weight drug compounds in tissue samples, and displays the spatial distribution of drugs within tissue samples from a human or other animal. This information can be used to determine whether a drug is reaching its intended target site within the tissue sample or is accumulating in the targeted tissue. Traditionally researchers attached radioactive molecules to small molecule drugs to track where the drug went and accumulated in the body. However, attaching the radioactive molecules can alter the drug properties, including where it goes in the body, frequently leading to inaccurate tissue distribution and toxicology information. Applied Biosystems believes Tissue Imaging by mass spectrometry represents a breakthrough technology for monitoring the safety and efficacy of small molecule drugs because it does not alter the properties of the drugs being studied.

Cell Biology and Functional Proteomics Products

Applied Biosystems has developed, and expects to continue developing, products used for the study of cell and biological molecule function. Applied Biosystems intends to market existing products and develop new products within this field. These products are intended for use by researchers studying the complex biological reactions that take place in cells, which researchers refer to as biological pathways, and how these pathways relate to human disease. These studies are needed in a variety of fields, including in particular drug discovery and development. Applied Biosystems currently offers the 8200 Cellular Detection System, which is used by researchers to study cellular function. The system uses proprietary scanning technology to rapidly detect and measure fluorescence associated with objects as small as a single cell. Applied Biosystems also markets a line of Tropix® chemiluminescent reagent products used by

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researchers studying cell function. Chemiluminescence is the conversion of chemical energy stored within a molecule into light, and the detection of chemiluminescence is another technology used to study cellular function. Applied Biosystems also licenses its chemiluminescence technology for adaptation for various types of diagnostic tests and drug discovery assays. These chemiluminescent-based tests and assays can be used in combination with a variety of detection instruments.

During our 2002 fiscal year, Applied Biosystems entered into a licensing, supply, and collaboration agreement with HTS Biosystems, Inc. to jointly develop and commercialize a functional proteomics system based on HTS Biosystems surface plasmon resonance and high-throughput affinity screening technologies. Pursuant to this agreement, the parties developed, and Applied Biosystems began marketing, a proteomics instrument referred to as the 8500 Affinity Chip Analyzer. However, in June 2004 Applied Biosystems decided to exit this product line based on a strategic analysis of various business and technology investments. Accordingly, Applied Biosystems exercised its right to terminate the agreement with HTS Biosystems and return rights to the product line and related technology to HTS Biosystems. The termination will be effective no later than November 30, 2004.

Applied Genetic Analysis Products

Applied Biosystems has developed, and expects to continue developing, products and services specially designed for specific markets, with a focus in the areas of human identification, biosecurity, and environmental and food testing.

For example, Applied Biosystems develops systems that are used by crime laboratories and other agencies to identify individuals based on their DNA, commonly referred to as forensic analysis. Applied Biosystems forensic analysis systems are used in criminal cases where DNA extracted from biological evidence found at the crime scene is compared with DNA from suspects or profiles stored in databases of potential suspects. The use of DNA in some criminal investigations has been shown to help solve crimes and reduce the cost of the investigation, and we believe there is a growing recognition of the validity of the use of DNA testing and DNA databases for this purpose. This is evidenced in particular by a growing number of governmental initiatives in the U.S. and abroad to finance the analysis of DNA from crime scenes, including the existing backlog of samples from past crimes, and build databases of potential suspects. This is also evidenced by the increasing use of DNA analysis to exonerate individuals previously convicted of crimes by testing archived evidence. Applied Biosystems forensic analysis systems are also used to identify human remains, and for paternity testing. During our 2004 fiscal year, Applied Biosystems began marketing a new system to increase the efficiency and effectiveness of forensic analysis by providing a qualitative and quantitative assessment of DNA in a sample prior to forensic analysis. This assessment can be used by scientists and technicians performing forensic analysis to facilitate proper sample preparation for analysis, which can reduce the risk that analysis must be repeated, and Applied Biosystems believes its new system provides more accurate and useful results than systems offered by other companies that are used for forensic analysis.

Also, Applied Biosystems is developing technologies for bacterial and fungal detection, characterization, and identification. It offers the MicroSeq® Microbial Identification System to accurately identify microorganisms. It also offers TaqMan® Pathogen Detection Systems, which operate on real-time PCR systems instruments, to rapidly detect bacterial contamination and detect and analyze genetically modified organisms in foods.

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Applied Biosystems has entered into several contracts to manufacture products needed in response to the threat of biological terrorism, often referred to as the biothreat or biosecurity market. For example, Applied Biosystems entered into a contract to manufacture an Anthrax bacteria detection product that another company has contracted to install and maintain in select U.S. Postal Service mail sorting centers. Applied Biosystems is evaluating the market for biosecurity products and may develop or manufacture other products for this market if and when it identifies other opportunities.

Information Products, including the Celera Discovery System

Applied Biosystems currently offers, and intends to further develop, products that offer information content designed to assist research and development efforts. The information products that Applied Biosystems currently licenses to customers include the Celera Discovery System, as well as software, for use in combination with the Applied Biosystems assay products, designed to facilitate and make more efficient experiment design and biological data analysis. The Celera Discovery System is an online information and discovery system through which users can access genomic and related biological and medical information, and which links users to information on Applied Biosystems genomics products. The system was originally developed and marketed by Celera Genomics, but Applied Biosystems is now the exclusive distributor of this system pursuant to an agreement that is described below in Item 1 of this report under the headings Applied Biosystems Group Business Marketing and Distribution Agreement with Celera Genomics.

In February 2004, Applied Biosystems launched a new release of the Celera Discovery System that includes enhanced visualization and analysis tools for comparing the human, mouse, and rat genomes and additional data integration. Significant features added with this new release include the ability to directly compare the versions of these three genomes that have been sequenced by Celera Genomics and the publicly-funded Human Genome Project. Also, as part of Applied Biosystems iScience strategy and mission of providing whole-product solutions to its customers, Applied Biosystems now offers several systems with online links to relevant biological information available by subscription, including the 1700 Chemiluminescent Microarray Analyzer, 4700 Proteomics Discovery System, QSTAR® XL Hybrid LC/MS/MS System, Q TRAP® LC/MS/MS System, and the 4000 Q Trap® LC/MS/MS System.

Informatics Products and Services

Applied Biosystems develops, markets, and distributes informatics software and services used to integrate and automate life sciences research, development, and manufacturing laboratories with the goal of increasing their efficiency and effectiveness. Users of Applied Biosystems informatics products and services are typically involved in gene mapping, drug discovery, drug development, and drug manufacturing. Applied Biosystems offers various software products for laboratory information management systems, often referred to as LIMS. These products are designed to facilitate sample tracking, data collection, data analysis, and data mining, and are generally designed to assist researchers in transforming data into useful information. Applied Biosystems also offers informatics consulting services directly through its Professional Services Group and through alliances with other companies. These consulting services are designed for laboratories seeking greater automation and integration of lab processes. Applied Biosystems consultants principally provide installation and customization of Applied Biosystems LIMS software offerings, and also can assist customers in selecting and

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integrating technologies to streamline and accelerate their genomics, proteomics, and high throughput screening activities.

Service and Support

Applied Biosystems provides warranties on all equipment at the time of sale, for periods of time ranging up to two years from the date of sale depending on the product subject to warranty. The warranties cover equipment installation, customer training, and application support. Applied Biosystems also offers service contracts to its customers that are generally one year after the original warranty period, but may range up to three years after the original warranty period. Applied Biosystems provides both repair services and routine maintenance services under these arrangements, and also offers repair and maintenance services on a time and material basis to customers that do not have service contracts. Service in the U.S. and major markets outside of the U.S. is provided by Applied Biosystems service staff. In some foreign countries, service is provided through distributorship arrangements.

Marketing and Distribution

General. The markets for Applied Biosystems products and services span the spectrum of the life sciences industry and research community, including: basic human disease research and genetic analysis performed by universities, government agencies, and other non-profit organizations; pharmaceutical drug discovery, development, and manufacturing; human identification; agriculture; biosecurity; and food and environmental testing. Each of these markets has unique requirements and expectations that Applied Biosystems seeks to address in its product offerings. Applied Biosystems customers are continually searching for processes and systems that can perform tests faster, more efficiently, and at a lower cost. Applied Biosystems believes that its focus on automated and high-throughput systems enables it to respond to these needs.

The size and growth of Applied Biosystems markets are influenced by a number of factors, including:

technological innovation in methods for analyzing biological data;

government funding for basic and disease-related research, such as in heart disease, AIDS, and cancer;

application of biotechnology to basic agricultural processes;

increased awareness of biological contamination in food and the environment; and

research and development spending by biotechnology and pharmaceutical companies.

In the U.S., Applied Biosystems markets the largest portion of its products directly through its own sales and distribution organizations, although some products are marketed through independent distributors and sales representatives. Sales to major markets outside of the U.S. are generally made by Applied Biosystems foreign-based sales and service staff, but are also made directly from the U.S. to foreign customers in some cases. In some foreign countries, sales are made through various representative and distributorship arrangements. Applied

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Biosystems owns or leases sales and service offices in the U.S. and in foreign countries through its foreign sales subsidiaries and distribution operations. None of Applied Biosystems products are distributed through retail outlets.

Applied Biosystems Portal. During our 2003 fiscal year, Applied Biosystems decided to expand the role of the Internet in both the marketing and distribution of its products and services and also generally educating and interacting with its customers. In furtherance of that decision, Applied Biosystems has since developed an Internet Portal, which consists primarily of the following two linked websites:

The Applied Biosystems website for electronic commerce, or e-commerce, which is located at www.appliedbiosystems.com. This website existed prior to the initiation of the Portal strategy but it was updated during our 2004 fiscal year.

The myScience℠ website, an Internet virtual research community which is located at myscience.appliedbiosystems.com. This website, which was launched during our 2004 fiscal year, is a free online resource that offers access to search tools and graphical viewers intended to help scientists plan their experiments, including selection of genomic reagents such as the Applied Biosystems TaqMan® gene expression and genotyping assays. The myScience Internet website also offers fee-based access to the entire Celera Discovery System for an in-depth interpretation and analysis of experimental results.

Applied Biosystems designed its Portal to link research resources directly to an online ordering system for Applied Biosystems products, and it has become a source of direct sales, particularly of its genomics products. The myScience website now includes features to browse and select for purchase a number of Applied Biosystems products, including TaqMan® Gene Expression and SNP Genotyping Assays, TaqMan® Low Density Arrays, the SNPlex Genotyping System, and the VariantSEQr Resequencing System. Applied Biosystems intends to phase additional features into its Portal over the next several fiscal years, and may consult or partner with third parties for this with the goal of creating a more effective Internet presence.

Marketing and Distribution Agreement with Celera Genomics

During our 2002 fiscal year, Applied Biosystems formed a Knowledge Business to develop and market products and services designed to meet the needs of life science researchers in performing specific biological analysis applications. The Knowledge Business was focused on generating value to life science customers through products and services with high information content that support improved experimental work-flows. Concurrently with Applied Biosystems formation of the Knowledge Business, in April 2002, Celera Genomics and Applied Biosystems entered into a ten-year marketing and distribution agreement pursuant to which Applied Biosystems became the exclusive distributor of Celera Genomics Celera Discovery System and related human genetic and other biological and medical information. As a result of this arrangement, Applied Biosystems has been integrating the Celera Discovery System and other genomic and biological information into its product offerings. During the second quarter of our 2004 fiscal year, Applied Biosystems reorganized its internal operations and, among other things, integrated the operations of the former Knowledge Business into other business units of Applied Biosystems. However, Applied Biosystems and Celera Genomics continue to operate under the marketing and distribution agreement on the same terms and conditions as in effect prior to the reorganization.

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In exchange for the rights it acquired under the marketing and distribution agreement, Applied Biosystems agreed to pay royalties to Celera Genomics based on revenues generated by sales of some Applied Biosystems products from July 1, 2002, through the end of our 2012 fiscal year. The royalty rate is progressive, up to a maximum of 5%, with the level of sales through our 2008 fiscal year. The royalty rate becomes a fixed percentage of sales starting in our 2009 fiscal year, and the rate declines each succeeding fiscal year through our 2012 fiscal year. The products subject to the royalties include:

- TaqMan® Gene Expression and SNP Genotyping Assays, TaqMan® Pre-Designed Gene Expression and SNP Genotyping Assays, and Custom TaqMan® Gene Expression and SNP Genotyping Assays;
- Some reagents for arrays; and
- New database subscriptions sold by Applied Biosystems.

Under the terms of the marketing and distribution agreement, Celera Genomics receives all revenues under, and is responsible for all costs and expenses associated with, Celera Discovery System and related information contracts that were entered into on or prior to June 30, 2002. However, Applied Biosystems took full responsibility for marketing and contracting for the Celera Discovery System and related products after that date. Accordingly, Celera Genomics does not expect any revenues from the Celera Discovery System and related products and services other than under contracts existing on that date, so long as they remain in effect, and from potential royalty payments from Applied Biosystems under the marketing and distribution agreement. Applied Biosystems has agreed to reimburse Celera Genomics for any shortfall in earnings before interest, taxes, depreciation, and amortization from these contracts below $62.5 million during the four fiscal years ending with the 2006 fiscal year, if the shortfall is due to the actions of Applied Biosystems including changes in marketing strategy for the Celera Discovery System. However, this commitment is also subject to Celera Genomics otherwise continuing to perform under these contracts, and does not protect Celera Genomics from lost revenue due to other circumstances such as customer bankruptcy or default.

Raw Materials

There are no specialized raw materials that are particularly essential to the operation of Applied Biosystems business. Applied Biosystems manufacturing operations require a wide variety of raw materials, electronic and mechanical components, chemical and biochemical materials, and other supplies, some of which are occasionally found to be in short supply. Applied Biosystems has multiple commercial sources for most components and supplies, but it is dependent on single sources for a limited number of such items, in which case Applied Biosystems normally secures long-term supply contracts. In some cases, if a supplier discontinues a product, it could temporarily interrupt the business of Applied Biosystems.

Patents, Licenses, and Franchises

Applied Biosystems products are based on complex, rapidly developing technologies. Some of these technologies are covered by patents owned by Applied Biosystems, and others are owned by third parties and are used by Applied Biosystems under license. Applied Biosystems has pursued a policy of seeking patent protection in the U.S. and other countries for

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developments, improvements, and inventions originating within its organization that are incorporated into Applied Biosystems products or that fall within its fields of interest. Applied Biosystems business depends on its ability to continue developing new technologies which can be patented, or licensing new technologies from third parties that own patents in desired technologies. The rights that Applied Biosystems considers important to its current business include the following:

Applied Biosystems licenses rights to PCR technology under a series of agreements with Hoffmann-La Roche Inc. and its affiliates, which own some of the patents covering the PCR process. Applied Biosystems receives royalties from third-party sales of products incorporating this technology through a series of licensing programs that it has established for industry access to some of its intellectual property. The first of these patents expires in March 2005 in the U.S., and in March 2006 in Europe and some other jurisdictions. The expiration of these patents may result in reduced royalty payments to Applied Biosystems. However, Applied Biosystems expects that a possible reduction in PCR royalties would be offset to a substantial degree by income from real-time PCR and other PCR-related technologies that it owns or licenses. In addition, Applied Biosystems has rights to multiple other PCR-related patents that should support a PCR-related royalty stream beyond our 2005 and 2006 fiscal years. Taken together, Applied Biosystems believes these factors should mitigate the effects of the patent expirations. The agreements with Hoffmann-LaRoche Inc. and its affiliates are the subject of legal proceedings described below in Item 3 of this report under the heading Roche. The outcome of legal proceedings is inherently uncertain, and an adverse outcome in these proceedings could negatively affect the value of our PCR rights.

Applied Biosystems also licenses rights under some patents assigned to the California Institute of Technology relating to DNA sequencing. These patents expire between 2009 and 2018 in the U.S., and in 2005 in Europe and some other jurisdictions.

From time to time, Applied Biosystems has asserted that various competitors and others are infringing its patents; and similarly, from time to time, others have asserted that Applied Biosystems was or is infringing patents owned by them. These claims are sometimes settled by mutual agreement on a satisfactory basis and result in the granting of licenses by or to Applied Biosystems. However, we cannot make any assurances as to the outcome of any pending or future claims.

Backlog

Applied Biosystems total recorded backlog at June 30, 2003, was $252.5 million, which included $1.2 million of orders from Celera Genomics and $3.1 million of orders from Celera Diagnostics. Applied Biosystems total recorded backlog at June 30, 2004, was $237.9 million, which included $1.5 million of orders from Celera Genomics and $1.8 million of orders from Celera Diagnostics. Recorded backlog may not result in sales because of cancellation or other factors. It is anticipated that most of the orders included in backlog at June 30, 2004, will be delivered before the close of our 2005 fiscal year.

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Competition

The markets in which Applied Biosystems operates are highly competitive and are characterized by the application of advanced technology. A number of Applied Biosystems competitors are well known manufacturers with a high degree of technical proficiency. In addition, competition is intensified by the ever-changing nature of the technologies in the industries in which Applied Biosystems is engaged.

Applied Biosystems principal competition comes from specialized manufacturers that have strengths in narrow segments of the life science markets. Applied Biosystems competes principally in terms of the breadth and quality of its product offerings, and its service and distribution capabilities. While the absence of reliable statistics makes it difficult to determine Applied Biosystems relative market position in its industry segment, Applied Biosystems believes it is one of the principal suppliers in its fields, marketing a broad line of instruments and life science systems.

Research, Development, and Engineering

Applied Biosystems is actively engaged in basic and applied research, development, and engineering programs designed to develop new products and to improve existing products. Research, development, and engineering expenses for Applied Biosystems totaled $219.6 million in our 2002 fiscal year, $238.4 million in our 2003 fiscal year, and $233.8 million in our 2004 fiscal year. Applera expensed $381.9 million in our 2002 fiscal year, $401.5 million in our 2003 fiscal year, and $377.1 million in our 2004 fiscal year for Applera research, development, and engineering activities.

Applied Biosystems new products generally originate from four sources: internal research and development programs; external collaborative efforts with technology companies and individuals in academic institutions; devices or techniques that are generated in customers laboratories; and business and technology acquisitions.

Research and development projects at Applied Biosystems include: the development of improved electrophoresis techniques for DNA analysis; real-time PCR for nucleic acid quantification; innovative approaches to cellular analysis; sample preparation; information technologies; and mass spectrometry.

Environmental Matters

Applied Biosystems is subject to federal, state, and local laws and regulations regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, in those jurisdictions where Applied Biosystems operates or maintains facilities. Applied Biosystems does not believe that any liability arising under, or compliance with, environmental laws or regulations will have a material effect on its business, and no material capital expenditures are expected for environmental control.

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Celera Genomics Group Business

Overview

Celera Genomics is engaged principally in the discovery and development of targeted therapeutics for cancer, autoimmune, and inflammatory diseases. Celera Genomics is leveraging its proteomic, bioinformatic, and genomic capabilities to identify and validate drug targets, and to discover and develop small molecule therapeutics. Celera Genomics expects to use these capabilities, along with its molecular and cell biology, medicinal and computational chemistry, pharmacology, and other drug development technologies to optimize the potency, selectivity, and physical properties of new drug candidates. Celera Genomics is also seeking to advance therapeutic antibody and selected small molecule drug programs in collaboration with global technology and market leaders.

Celera Genomics and Celera Diagnostics are pursuing, in cooperation with each other, a strategy that we refer to as targeted medicine. This strategy is based on the belief that a better understanding of the genetic basis of biology and disease is key to improved diagnosis and treatment of many common complex diseases. Celera Genomics and Celera Diagnostics are applying research and development tools and methods to analyze biological information, including genetic variations discovered through the Applera Genomics Initiative, in an attempt to discover associations between genes and diseases. The Applera Genomics Initiative is described below in Item 1 of this report under the heading Applera Genomics Initiative. Celera Genomics may use this information to select and validate therapeutic targets for new drugs, and to stratify patient populations in clinical trials to increase the proportion of patients who have an efficacious response to drug treatment. Celera Diagnostics intends to develop new diagnostic tests based on known and newly-identified genetic and proteomic markers to help physicians predict an individual s predisposition to, better characterize, monitor progression of, and select appropriate therapy for, common complex diseases. The ultimate goal of this targeted medicine approach is to:

identify new and improved targets for drug discovery and development;

facilitate more efficient clinical trials of new therapeutics;

develop diagnostic tests that address unmet medical needs in predicting, detecting, characterizing, and monitoring diseases; and

use diagnostics to select a form of therapy that is likely to be more effective and possibly safer in a particular patient population.

Celera Genomics may pursue both antibody and small molecule therapeutics. Antibodies are a type of protein produced by the human immune system that bind to potentially harmful substances, such as viruses and bacteria, in order to disable and eliminate them. Antibody therapeutics, thus, are protein-based biological compounds that are designed to similarly bind to and interfere with the activities of a particular target. Celera Genomics has initially chosen to focus on the discovery of proteins found primarily on the surface of tumor

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cells as potential targets for antibody therapeutics. Small molecule therapeutics are generally low molecular weight, synthetically derived chemical compounds designed to bind to and interfere with the activities of particular targets, such as proteins, DNA, or RNA.

Development of Therapeutics Business

Celera Genomics was originally formed for the purpose of generating and commercializing information to accelerate the understanding of biological processes and to assist the research endeavors of pharmaceutical, biotechnology, and life science research entities. A key component of Celera Genomics original business strategy was the development and sale of its Celera Discovery System , an online information and discovery system through which users can access Celera Genomics genomic and related biological and medical information. The Celera Discovery System is now marketed by Applied Biosystems under a marketing and distribution agreement, which is described above in Item 1 of this report under the headings Applied Biosystems Group Business Marketing and Distribution Agreement with Celera Genomics.

During our 2001 fiscal year, Celera Genomics expanded its operations to include therapeutics discovery and development in addition to its online database business, and since then has established the therapeutics business as its primary focus. In December 2002, Celera Genomics announced a refined business and scientific plan for its therapeutics business which generally provides for increased investment in clinical development capabilities, and greater efficiency and economy in target discovery, while continuing to place emphasis on Celera Genomics cash as a strategic asset. In support of this plan, Celera Genomics has hired key managers and staff for the therapeutics business.

During our 2004 fiscal year, Celera Genomics continued to develop its therapeutics business. Celera Genomics scientists advanced several small molecule therapeutic programs, including its histone deacetylase, or HDAC, program for cancer and its Factor VIIa anticoagulation program, both of which are described below in Item 1 of this report under the headings Celera Genomics Group Business Small Molecule Drug Programs Compound Development Programs. Also, during our 2004 fiscal year, Celera Genomics made significant progress in its proteomic studies of pancreatic, lung, and colon cancer and began processing breast tissue samples. These studies are described below in Item 1 of this report under the headings Celera Genomics Group Business Target Discovery Programs; Proteomics and Genomics Research Proteomics Studies.

Also, in July 2004, subsequent to the end of our 2004 fiscal year, Celera Genomics announced several developments in its business, which are described below:

Celera Genomics announced the formation of a strategic collaboration with Abbott Laboratories to discover, develop, and commercialize therapies for the treatment of cancer. The collaboration will encompass the development of various therapeutic approaches, including antibodies and small molecule drugs targeted against differentially-expressed cell-surface proteins that have been associated with cancer and validated as therapeutic targets through Celera Genomics proteomics research.

Celera Genomics announced along with Celera Diagnostics a joint research collaboration with General Electric Company intended to accelerate the

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discovery and development of new products for personalized, or targeted, medicine. The parties will seek to understand and differentiate disease at the molecular level, which is expected to lead to new diagnostics and treatments that are tailored for a specific disease or patient population. The first project outlined in the research collaboration is intended to support General Electric s development of novel imaging agents that selectively target cell surface proteins that Celera Genomics has identified to be associated with cancer. A second project is intended to apply bioinformatics techniques to the prioritization of targets for diagnostic and therapeutic use.

Celera Genomics announced receipt of a milestone payment from Merck & Co. Inc. under the cathepsin K inhibitor collaboration agreement between the companies. This research program is described below in Item 1 of this report under the headings Celera Genomics Group Business Small Molecule Drug Programs Compound Development Programs. This payment recognizes Merck s advancement of a cathepsin K inhibitor into Phase I clinical trials as a potential treatment for osteoporosis. If this compound or others developed under the cathepsin K collaboration are successfully developed and advanced toward commercialization, which requires several other clinical trials if Phase I trials are successful, Celera Genomics will receive additional milestone payments and royalties on net sales from Merck.

Celera Genomics announced a strategic collaboration with Seattle Genetics, Inc. to jointly discover and develop antibody-based therapies for cancer. Pursuant to the collaboration, the parties will jointly designate a number of cell-surface proteins discovered and validated through Celera Genomics proteomics research as targets. Seattle Genetics will carry out initial screening to generate and select the appropriate corresponding antibodies for joint development and commercialization. Antibodies developed under this collaboration may include Seattle Genetics proprietary antibody-drug conjugates, which are antibodies carrying cell-killing drugs. These antibodies may not be potent enough to kill cancer cells but can target cancer cells and deliver the cell-killing or cytotoxic, drugs.

Target Discovery Programs; Proteomics and Genomics Research

Overview. Therapeutic target discovery, including identification and validation research, continues to be an important part of Celera Genomics business, although it has directed its resources primarily to small molecule therapeutics development. Therapeutic targets are biological points of intervention for a therapeutic designed to affect a particular disease or medical condition. Validation refers to the process whereby the biological relevance of a particular target, and, therefore, its potential therapeutic relevance, is confirmed by conducting additional, complementary testing or analysis. Celera Genomics is focusing its target discovery research efforts in two areas: proteomics studies, which are described further below under the heading Proteomics Studies, and analysis of the results of Celera Diagnostics gene-disease association studies, which are described below in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Research and Development. Celera Genomics believes that these research efforts may lead to several possible commercial uses, which are described below:

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Currently, the primary purpose of these research efforts is to identify and validate targets for antibody therapeutics and small molecule therapeutics. Celera Genomics has entered into collaborations to support these development efforts, including an antibody and small molecule therapeutic collaboration with Abbott Laboratories, and an antibody therapeutic collaboration with Seattle Genetics. Both of these collaborations are for development of therapeutics targeted to cell-surface proteins associated with cancer. These collaborations are described above in Item 1 of this report under the headings Celera Genomics Group Business Development of Therapeutics Business. Generally, Celera Genomics is seeking to defer the need to partner on small molecule drugs, if at all, other than those covered by the Abbott Laboratories collaboration. On the other hand, Celera Genomics believes it will likely collaborate with other companies on most or all antibody therapeutics that it may pursue as it is not currently seeking to build the infrastructure needed for their internal development. Celera Genomics development capabilities and expansion plans are described below in Item 1 of this report under the headings Celera Genomics Group Business Small Molecule Drug Programs.

Validated targets discovered through Celera Genomics research may be useful as *in vitro* or *in vivo* diagnostics, whether or not they result in efficacious therapeutics. *In vitro* refers to testing or other activities performed outside the living body, and *in vivo* refers to testing or other activities performed in the living body. In July 2004, Celera Genomics and Celera Diagnostics announced a collaboration with General Electric pursuant to which General Electric may develop novel *in vivo* imaging agents targeted to cell surface proteins that Celera Genomics has identified to be associated with cancer. This collaboration is described above in Part I of this report under the headings Celera Genomics Group Business Development of Therapautics Business. Celera Genomics expects that any *in vitro* diagnostics derived from Celera Genomics research would be commercialized, if at all, through Celera Diagnostics because these types of diagnostics are currently within Celera Diagnostics field of business.

Also, Celera Genomics is seeking to incorporate its study of pharmacogenomics into the design of clinical studies. Pharmacogenomics, a term which refers to the combination of pharmacology and genomics, is the study of how an individual s genetic inheritance affects the body s response to drugs. Celera Genomics believes that its pharmacogenomics research, which includes its analysis of the results of Celera Diagnostics gene-disease association studies, may generate information that is useful in stratifying patient populations to increase the proportion of patients who have an efficacious response to drug treatment.

Proteomics Studies. Celera Genomics uses high-throughput proteomics to identify proteins that are associated with disease. These proteins may be targets for therapeutic intervention. Celera Genomics current proteomics efforts are focused on analyzing proteins on the surface of cells from both healthy and diseased individuals, seeking to identify proteins that can be associated with particular diseases. These cell surface proteins, which are referred to as differentially-expressed cell-surface proteins, are the class of proteins believed to represent the most promising targets for near-term drug candidates in the form of therapeutic antibodies. However, Celera Genomics has recently begun studying proteins that are shed from cancer cells within the body, as it believes this may also be a class of proteins that could result in drug targets or diagnostic tests. The diseases that Celera Genomics has initially selected for

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proteomics study are pancreatic, lung, colon, and breast cancer. Celera Genomics conducts its proteomics research at its own proteomics facility, which became fully operational during our 2003 fiscal year.

During our 2004 fiscal year, Celera Genomics made significant progress in its proteomic studies of pancreatic, lung, and colon cancer and began processing breast tissue samples. As a result of these studies, Celera Genomics successfully identified over 200 differentially-expressed proteins on the surface of cancer cells. Its scientists are now completing validation studies for several of these proteins as potential therapeutic targets for treating pancreatic cancer. They have also selected additional differentially expressed proteins for validation, including our first potential therapeutic targets related to lung and colon cancers.

In order to identify differentially expressed cell-surface proteins, Celera Genomics has designed advanced methods to separate cellular and subcellular components of biological samples. Celera Genomics uses advanced mass spectrometer systems that are amenable to high-throughput quantitation and identification of proteins from separated biological samples. Celera Genomics is also using its assembled human genome and proprietary software and algorithms to identify proteins associated with diseases.

For target validation, Celera Genomics uses a variety of methodologies. In collaboration with other companies, Celera Genomics uses immunohistochemistry, or the identification of proteins in tissues and cells using antibodies, to refine its understanding of therapeutic targets of interest and, for example, to identify protein expression profiles that would support or preclude meaningful progression of the drug targets. For targets of interest, Celera Genomics intends to perform tests to determine their relevance across a broad range of tissues and diseases. Celera Genomics expects to continue accessing further validation capabilities through collaborations.

Bioinformatics. As a result of its prior activities in sequencing the human and other genomes and creating and maintaining the Celera Discovery System, Celera Genomics has substantial bioinformatics resources. Using these resources, Celera Genomics expects to develop the capability to perform simulated, computer-based experimentation, which Celera Genomics believes would minimize the need to perform more labor-intensive experiments in the laboratory. Also, Celera Genomics believes that it can develop proprietary algorithms for use in its large scale computing infrastructure for the extraction of data from proteomics experiments and the integration of this data with genome, gene expression, and protein characterization information, scientific literature, and the patent status of possible targets. Celera Genomics believes the application of these algorithms to this data could be used to facilitate the identification of targets. However, Celera Genomics ability to develop these capabilities is unproven, and, if developed, their utility in the therapeutics discovery and development process is uncertain.

Genomics Studies. Also as a result of its prior activities, Celera Genomics has substantial genomics capabilities. As a complementary approach to the proteomics methods and the disease association studies described above, Celera Genomics uses genomics in its efforts to identify and validate therapeutic targets. Celera Genomics intends to further characterize recently discovered genes, including those for which we have been issued patents or for which we have filed patent applications, by conducting *in vitro* cell studies and *in vivo* animal studies. Celera Genomics expects to incorporate its bioinformatics capabilities into this process. After the functions of genes are determined, Celera Genomics intends to establish the priorities of these genes or their gene products as targets based on the families of proteins they encode, the

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association of the expression of these genes with specific diseases, and the functional importance of the gene products to cells.

Small Molecule Drug Programs

Celera Genomics has a small molecule drug discovery and development facility in South San Francisco, California. At this facility, Celera Genomics is performing research to identify and validate potential small molecule therapeutic targets and develop small molecule therapeutic compounds. Celera Genomics originally acquired some of these capabilities with its acquisition of Axys Pharmaceuticals, Inc. in November 2001. Since the acquisition, Celera Genomics has developed additional capabilities and intends to continue doing so, particularly by expanding its small molecule drug development capabilities. Celera Genomics small molecule drug research and development expertise and programs are described below.

Scientific Expertise For Lead Compound Identification. Celera Genomics has a range of chemistry and biology capabilities which have been used primarily for therapeutic compound discovery and development. To date, a primary focus of Celera Genomics chemists and biologists has been lead compound discovery and development using a variety of methods. Lead compounds are those within a series of related compounds that we believe are the most promising and which we would seek to move into preclinical and clinical development. Currently, Celera Genomics lead compound discovery and development efforts are focused on both structure-based drug design and high-throughput screening. These methods are generally described as follows:

Structure-based Drug Design. Structure-based drug design is a process whereby medicinal chemists attempt to develop compounds that will bind to a therapeutic target based on the physical 3-dimensional structure of the target molecule. Our medicinal chemists obtain this information by analyzing pictures of the molecule taken through X-ray crystallography and also by performing molecular modeling based on the known properties of the components of the target molecule.

High-Throughput Screening. High-throughput screening involves the screening of thousands of compounds against a disease target, usually a protein, to determine whether and how any of them bind to the target. Axys developed and purchased compound libraries for these studies and Celera Genomics has continued to diversify its compound libraries through the purchase of additional compound collections.

Compound Development Programs. Using the technologies described above, Celera Genomics has developed a general expertise in discovering and developing potential therapeutic compounds that target proteases, a known druggable class of proteins. Proteases are enzymes that break down chemical bonds in proteins and are essential to the body s physiological processes such as inflammation. Proteases are generally classified by how they break down a protein s chemical bonds. Cysteine and serine proteases are two classes of these enzymes.

Celera Genomics has discovered inhibitors of some of the proteases that it has studied. Inhibitors are natural or synthetic compounds that can bind to the protein molecule and change the way it will perform in the body, and in particular, can prevent the function of the target protease that is causing or contributing to a particular disease or condition. Celera Genomics is developing several inhibitors on its own, and has two collaborations with major pharmaceutical

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companies for the development of therapeutics for inflammatory diseases. These internal and partnered programs include the following:

Celera Genomics has an internal program to develop inhibitors of Factor VIIa, a serine protease, as an anticoagulant for the treatment of indications such as deep vein thrombosis, with the goal of improved balance between bleeding time and therapeutic efficacy compared to existing therapies.

Celera Genomics has another internal program to develop inhibitors of histone deacetylase, or HDAC. HDAC is an enzyme that is involved in the regulation of histone acetylation, a biological process that influences gene expression. Inhibition of HDAC leads to an increase in gene expression in a number of genes, some of which are related to cell cycle arrest and cell death. Medicinal chemists at Celera Genomics have applied structure based drug design to generate compounds that possess potent *in vitro* inhibition of HDAC activity, and *in vivo* efficacy in models of cancer.

Celera Genomics has two partnered programs that it acquired with Axys Pharmaceuticals. The first is a collaboration with Merck & Co. Inc. to develop small molecule inhibitors of cathepsin K, a cysteine protease, for the treatment of osteoporosis. Osteoporosis is a major risk factor for bone fractures and associated disability that affects over 10 million Americans, especially post-menopausal women. The second is a collaboration with Aventis Pharmaceuticals to develop inhibitors of cathepsin S, another type of cysteine protease. Celera Genomics portion of both programs has been completed, and further development of therapeutics is now the responsibility of the partners, who will make clinical development decisions. In July 2004, Celera Genomics announced receipt of a milestone payment from Merck & Co. Inc. under the cathepsin K program. This payment recognizes Merck s advancement of a cathepsin K inhibitor into Phase I clinical trials as a potential treatment for osteoporosis. Under U.S. Food and Drug Administration regulations, if these trials are successful several other clinical trials would be required before the compound could be commercialized.

Celera Genomics also has an internal program to develop inhibitors of tryptase, a serine protease, for the treatment of asthma. Celera Genomics previously had a collaboration with Bayer AG but during the 2003 fiscal year purchased all rights to the compounds subject to the collaboration. Since then, Celera Genomics discontinued its development of the lead compound series that had been acquired from Bayer and has shifted its efforts in this program to new proprietary compounds developed using, in part, technology and expertise obtained from the Bayer collaboration and the purchase of rights from Bayer.

Development of Preclinical and Clinical Resources and Expertise. A key element of Celera Genomics business and scientific plan is to increase its therapeutic development capabilities for both preclinical and clinical activities so that its most promising therapeutic programs can be advanced into clinical trials without having to partner with other companies. At Celera Genomics, a compound is considered to be in preclinical development when it has been identified as a lead compound within a series of compounds and Celera Genomics begins its efforts to assess and enable the effectiveness of the compound within the human body; and is considered to be in clinical development when clinical trials begin. Celera Genomics preclinical

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programs are described above in Item 1 of this report under the headings Celera Genomics Group Business Small Molecule Drug Programs Compound Development Programs. It does not currently have any non-partnered compounds in clinical development.

When acquired by Celera Genomics, Axys had some preclinical development capabilities, particularly in the scientific area of pharmacokinetics, and no significant clinical development capabilities. Since the Axys acquisition, Celera Genomics has substantially increased its scientific personnel to support preclinical and clinical activities, particularly the following:

drug metabolism, pharmacokinetics, and other personnel to evaluate how a compound is absorbed into the body; distributed within the body; metabolized, or broken down, once introduced into the body; and excreted, or eliminated, by the body;

toxicology personnel to perform studies to determine the safety of compounds; and

pharmaceutical sciences personnel to focus on the conversion of a compound into an acceptable physical form for administration to animals or humans, for example an injection in the skin or a pill or liquid taken orally.

In addition to the areas of scientific expertise described above, Celera Genomics has hired limited personnel in other areas that are important for drug development, including: clinical sciences personnel, who are involved in the overall direction and management of clinical development and the execution of clinical trials; regulatory affairs personnel, who have expertise in U.S. Food and Drug Administration and other pertinent regulations; and project management personnel, who help integrate the different drug development project teams and facilitate communications among these different teams.

Marketing and Distribution Agreement with Applied Biosystems; Celera Discovery System

In April 2002, Celera Genomics and Applied Biosystems entered into a ten-year marketing and distribution agreement pursuant to which Applied Biosystems became the exclusive distributor of Celera Genomics Celera Discovery System. Applied Biosystems is continuing to integrate the Celera Discovery System and other genomic and biological information into its products and services. The agreement has enabled Celera Genomics executive team to focus on therapeutics discovery and development. The agreement is described above in Item 1 of this report under the headings Applied Biosystems Group Business Marketing and Distribution Agreement with Celera Genomics. Important information about this agreement also appears later in Item 5 of Part II of this report under the headings Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Forward Looking Statements and Risk Factors. Under the marketing and distribution agreement, Celera Genomics continues to have access to all data, which may include formats not available to third parties, and other intellectual property associated with the Celera Discovery System for its therapeutic programs. Celera Genomics expects that such data and intellectual property will have a significant role in its product research and development.

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Raw Materials

Celera Genomics operations require a variety of raw materials, such as chemical and biochemical materials and other supplies, some of which are occasionally found to be in short supply. Any interruption in the availability of these materials could adversely affect Celera Genomics operations. In particular, Celera Genomics needs access to human and other tissue samples from diseased and healthy individuals, other biological materials, and related clinical and other information, which may be in limited supply. Celera Genomics may not be able to obtain or maintain access to these materials and information on acceptable terms, or may not be able to obtain needed consents from individuals providing tissue or other samples. In addition, government regulation in the U.S. and foreign countries could result in restricted access to, or use of, human and other tissue samples. If Celera Genomics loses access to sufficient numbers or sources of tissue samples or other required biological materials, or if tighter restrictions are imposed on its use of related clinical or other information or the information generated from tissue samples or other biological materials, its business may be harmed.

Patents, Licenses, Franchises and other Intellectual Property

Through its internal research programs and collaborative programs, Celera Genomics anticipates that it will develop an increasing portfolio of intellectual property. Celera Genomics may use this intellectual property in its internal development programs or may license such intellectual property to third party collaborators or customers for some combination of license fees, milestone payments, and royalty payments.

Celera Genomics competitive position depends on maintaining its intellectual property protection and obtaining licenses to intellectual property it may need from others. Celera Genomics ability to compete and to achieve and maintain profitability depends on its ability to protect its proprietary discoveries and technologies, in large part, through obtaining and enforcing patent rights, obtaining copyright protection, maintaining its trade secrets, and operating without infringing the intellectual property rights of others. Celera Genomics ability to obtain patent protection for its inventions is uncertain. The patentability of biotechnology and pharmaceutical inventions involves complex factual and legal questions. As a result, it is difficult to predict whether patents will be issued or the breadth of claims that will be allowed in biotechnology and pharmaceutical patents. This may be particularly true with regard to the patenting of gene sequences, gene functions, and genetic variations. In this regard, the U.S. Patent and Trademark Office has adopted guidelines for use in the review of the utility of inventions, particularly biotechnology inventions. These guidelines increased the amount of evidence required to demonstrate utility in order to obtain a patent in the biotechnology field, making patent protection more difficult to obtain. Although others have been successful in obtaining patents to biotechnology inventions, since the adoption of these guidelines, these patents have been issued with increasingly less frequency. As a result, patents may not be issued for patent applications that Celera Genomics may own or license if the applicant is unable to satisfy the new guidelines. Celera Genomics recognizes that many of the intellectual property laws are directly suitable for application to these discoveries while other protections may not be available or extend to cover genomic and/or proteomic-based discoveries.

Celera Genomics also cannot ensure that changes in policies or to laws, or interpretations thereof, relevant to the patenting of biotechnology inventions, including for example inventions relating to DNA, including SNP, protein, therapeutic, and diagnostic discoveries, will not adversely affect its patent position worldwide. Celera Genomics anticipates that there may be

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significant opposition worldwide regarding intellectual property rights for biotechnology inventions. This opposition may result in stricter standards for obtaining or enforcing biotechnology patent rights. Celera Genomics may become involved in opposition proceedings or litigation in order to obtain or enforce it intellectual property rights. If Celera Genomics becomes involved in these proceedings or litigation, it could consume a substantial portion of Celera Genomics resources, and Celera Genomics may not ultimately prevail and may not be able to prevent a competitor from making, using, or selling products or technology similar or identical to its own.

Celera Genomics itself may become involved in litigation with a third party seeking to enforce its own intellectual property rights. If Celera Genomics does not prevail in a patent litigation dispute, it may be required to pay damages or royalties or to take measures to avoid any future infringement.

Celera Genomics has filed for patent protection worldwide for inventions relating to its discoveries. Celera Genomics expects to continue seeking patent protection for inventions relating to its DNA, including SNP, protein, therapeutic, and diagnostic discoveries. Celera Genomics current strategy is to apply for patent protection for inventions that are made relating to novel pharmaceuticals and any novel formulations or methods of manufacture thereof, and novel methods of treating and diagnosing disease, as well as any novel inventions that may be made relating to DNA, including SNP, and protein discoveries. Although obtaining patent protection for inventions relating to its DNA, protein, and diagnostic discoveries might enhance Celera Genomics business, Celera Genomics does not believe that its commercial success will be materially dependent on its ability to do so. However, Celera Genomics failure to receive patent protection for its therapeutic inventions could adversely affect the commercial value of these discoveries. Celera Genomics currently owns 170 U.S. patents claiming inventions relating to its DNA, protein and therapeutic discoveries.

Celera Genomics also relies on trade secret protection for its confidential and proprietary information and procedures. Celera Genomics protects its trade secrets through recognized practices, including access control, confidentiality and nonuse agreements with employees, consultants, collaborators and customers, and other security measures. These confidentiality and nonuse agreements may be breached, however, and Celera Genomics may not have adequate remedies for a breach. In addition, Celera Genomics trade secrets may otherwise become known or be independently developed by competitors. Accordingly, it is uncertain whether Celera Genomics reliance on trade secret protection will be adequate to safeguard its confidential and proprietary information and procedures.

Backlog

Celera Genomics total recorded backlog at June 30, 2003, was $80.1 million. Celera Genomics total recorded backlog at June 30, 2004, was $25.2 million. Recorded backlog may not result in sales because of cancellation or other factors. It is anticipated that most of the orders included in backlog at June 30, 2004, will be delivered before the close of our 2005 fiscal year.

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Competition

The pharmaceutical industry is competitive and evolving. There is intense competition among pharmaceutical and biotechnology companies attempting to discover candidates for potential new therapeutic products. These companies may:

develop new therapeutic products in advance of Celera Genomics or its collaborators;

develop therapeutic products which are more effective or more cost-effective than those developed by Celera Genomics or its collaborators;

obtain regulatory approvals of their therapeutic products more rapidly than Celera Genomics or its collaborators; or

obtain patent protection or other intellectual property rights that would limit the ability of Celera Genomics or its collaborators to develop and commercialize therapeutic products.

Research and Development

Celera Genomics is actively engaged in basic and applied research and development programs designed to develop new therapeutic products and support the commitments of existing online/information contracts. Research and development expenses for Celera Genomics totaled $132.7 million in our 2002 fiscal year, $120.8 million in our 2003 fiscal year, and $104.6 million in our 2004 fiscal year. Applera expensed $381.9 million in our 2002 fiscal year, $401.5 million in our 2003 fiscal year, and $377.1 million in our 2004 fiscal year for Applera research, development, and engineering activities. Celera Genomics new products are expected to originate from three sources: internal research and development programs, external collaborative efforts or alliances, and business and technology acquisitions.

Environmental Matters

Celera Genomics is subject to federal, state, and local laws and regulations regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, in those jurisdictions where Celera Genomics operates or maintains facilities. Celera Genomics does not believe that any liability arising under, or compliance with, environmental laws or regulations will have a material effect on its business, and no material capital expenditures are expected for environmental control.

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Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics

Overview

Celera Diagnostics is engaged principally in the discovery, development, and commercialization of diagnostic products. In particular, Celera Diagnostics is studying SNPs and gene expression patterns in human biological tissues and blood samples and their association with specific common, complex diseases. These SNPs and gene expression patterns are often referred to as genetic markers. Celera Diagnostics gene-disease association studies are currently focused on the following disease areas: heart disease; breast cancer; Alzheimer s disease; autoimmune and inflammatory diseases, including rheumatoid arthritis; liver disease; and diabetes. In addition, Celera Diagnostics is conducting host response studies to identify genetic associations with patient response to treatments. Specifically, Celera Diagnostics is conducting these types of studies in patients infected with the Hepatitis C virus to identify patients who respond positively to interferon treatment, and in patients with heart disease to identify patients who respond to various types of treatment for that disease. Celera Diagnostics plans to conduct similar studies of this type in the future for other treatments and diseases. Celera Diagnostics expects that the discoveries resulting from its research will provide genetic information which may lead to earlier and more effective diagnosis and treatment of disease. Celera Diagnostics expects that the primary end-users of its products will be reference laboratories, hospitals, and medical clinics worldwide that perform diagnostic testing for human healthcare.

Celera Diagnostics and Celera Genomics are pursuing, in cooperation with each other, a strategy that we refer to as targeted medicine. This strategy is based on the belief that a better understanding of the genetic basis of biology and disease is key to improved diagnosis and treatment of many common complex diseases. Celera Diagnostics and Celera Genomics are applying research and development tools and methods to analyze biological information, including genetic variations discovered through the Applera Genomics Initiative, in an attempt to discover associations between genes and diseases. The Applera Genomics Initiative is described below in Item 1 of this report under the heading Applera Genomics Initiative. Celera Diagnostics intends to develop new diagnostic tests based on known and newly-identified genetic and proteomic markers to help physicians predict an individual s predisposition to, better characterize, monitor progression of, and select appropriate therapy for, common complex diseases. Celera Genomics may use this information to select and validate therapeutic targets for new drugs, and to stratify patient populations in clinical trials to increase the proportion of patients who have an efficacious response to drug treatment. The ultimate goal of this targeted medicine approach is to:

identify new and improved targets for drug discovery and development;

facilitate more efficient clinical trials of new therapeutics;

develop diagnostic tests that address unmet medical needs in predicting, detecting, characterizing, and monitoring diseases; and

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use diagnostics to select a form of therapy that is likely to be more effective and possibly safer in a particular patient population.

Development of Diagnostics Business

Celera Diagnostics was formed during our 2001 fiscal year pursuant to a joint venture agreement between Applied Biosystems and Celera Genomics. A description of that agreement is set forth below in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Summary of Joint Venture Agreement. Since its formation, Celera Diagnostics has achieved a number of important milestones in the development of its business including, among others: establishment of headquarters in Alameda, California; hiring of key personnel in areas of discovery research, product development, manufacturing, quality assurance, regulatory affairs, and marketing; construction of discovery laboratories and manufacturing facilities; commencement of large-scale study programs; formation of several important alliances, collaborations, and other third party relationships to support its research, development, and commercialization of products, including particularly its strategic alliance with Abbott Laboratories; and receipt of several marketing clearances for its ViroSeq HIV-1 Genotyping System from the U.S. Food and Drug Administration, or FDA. Key developments during our 2004 fiscal year included the following:

Between September 2003 and June 2004, Celera Diagnostics announced the discovery of, and publicly identified, a total of six genes that are markers associated with an increased risk for myocardial infarction, or heart attack. None of these genes were in a previously recognized disease pathway associated with myocardial infarction.

In October 2003, Celera Diagnostics announced a research collaboration with Merck & Co., Inc. to identify and validate genetic markers useful in Celera Diagnostics development of diagnostic tests and Merck s development of therapeutics for selected cancers. Pursuant to this collaboration agreement, the parties have agreed to share data and other intellectual property for use in their separate research and development efforts. The collaboration is initially focused on breast cancer but may be expanded to other cancers by mutual consent.

In November and December, 2003, at scientific meetings Celera Diagnostics and its collaborators presented selected results from three genomic studies, including preliminary findings regarding risk of distant metastasis in breast cancer, interferon responsiveness in hepatitis C patients, and Alzheimer s disease.

In February 2004, Celera Diagnostics announced that it obtained clearance from the FDA for expanded claims related to its ViroSeq HIV-1 Genotyping System. The ViroSeq system is described in further detail below in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Celera Diagnostics Products ViroSeq HIV-1 Genotyping System.

In June 2004, Celera Diagnostics announced the discovery of, and publicly identified, a SNP in a gene that is a marker associated with an increased risk for rheumatoid arthritis and its potential use as a new drug target.

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In June 2004, Celera Diagnostics announced, along with Applied Biosystems, a patent license agreement with Cepheid relating to real time thermal cycler instruments for research, diagnostic, and other uses. The terms of the agreement require Cepheid to pay Applera a license fee of $11.5 million over a two year period, the majority of which relates to the diagnostic rights granted to Cepheid and will be recorded by Celera Diagnostics. Also, under the terms of the agreement, Cepheid is obligated to pay ongoing royalties on sales of its products incorporating Applera intellectual property based on the field of use. We anticipate that the majority of sales will be in the diagnostic field and the corresponding royalties will be recorded by Celera Diagnostics.

Also, subsequent to the end of our 2004 fiscal year, in July 2004, Celera Diagnostics announced along with Celera Genomics a joint research collaboration with General Electric Company intended to accelerate the discovery and development of new products for personalized, or targeted, medicine. The parties will seek to understand and differentiate disease at the molecular level, which is expected to lead to new diagnostics and treatments that are tailored for a specific disease or patient population. The first project outlined in the research collaboration is intended to support General Electric s development of novel imaging agents that selectively target cell surface proteins that Celera Genomics has identified to be associated with cancer. A second project is intended to apply bioinformatics techniques to the prioritization of targets for diagnostic and therapeutic use.

Also in July 2004, Celera Diagnostics announced a collaboration agreement with Merck & Co., Inc. to identify novel drug targets and diagnostic markers related to Alzheimer s disease. Pursuant to the collaboration, Merck will fund Celera Diagnostics performance of expanded Alzheimer s gene-disease association research. Merck will be entitled to the therapeutic rights to targets identified for the treatment of Alzheimer s disease and some other neurological disorders, and Celera Diagnostics will retain rights to all diagnostic applications for markers identified.

Summary of Joint Venture Agreement

Celera Diagnostics was formed during our 2001 fiscal year as a joint venture between Applied Biosystems and Celera Genomics. In connection with the formation of Celera Diagnostics, Applied Biosystems contributed, among other things, its then-existing molecular diagnostics business to Celera Diagnostics, and Celera Genomics contributed, among other things, access to its genome databases. Also, Celera Genomics agreed to fund all of the cash operating losses of Celera Diagnostics up to a maximum of $300 million (initial losses), after which, operating losses, if any, will be shared equally by Applied Biosystems and Celera Genomics. Celera Diagnostics profits, if any, will be shared in the ratio of 65 percent to Celera Genomics and 35 percent to Applied Biosystems until the cumulative profits of Celera Diagnostics equal the initial losses. Subsequently, profits and losses and cash flows would be shared equally between Applied Biosystems and Celera Genomics. Applied Biosystems and Celera Genomics will fund Celera Diagnostics capital expenditures and working capital requirements equally. Applied Biosystems will reimburse Celera Genomics for all tax benefits generated by Celera Diagnostics to the extent such tax benefits are utilized by Applied Biosystems. In the event of liquidation of the assets attributable to Celera Diagnostics, including sale of these assets, the proceeds upon liquidation would be distributed to Applied Biosystems and Celera Genomics based on a proportion similar to their relative investment accounts. If the

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proceeds upon liquidation are in excess of the groups combined investment accounts, the excess liquidation proceeds would be shared in the ratio of 65 percent to Celera Genomics and 35 percent to Applied Biosystems until the cumulative amount of the distributed excess proceeds equals the initial losses funded by Celera Genomics. Any additional liquidation proceeds would be allocated equally to Celera Genomics and Applied Biosystems.

Abbott Laboratories Strategic Alliance

In June 2002, Celera Diagnostics announced a long-term strategic alliance with Abbott Laboratories, one of the world s largest diagnostics companies, to discover, develop and commercialize a broad range of *in vitro* diagnostic products for disease detection, prediction of disease predisposition, disease progression monitoring, and therapy selection. *In vitro* diagnostic products are diagnostic products that are used for testing outside of the living body. The agreement with Abbott Laboratories is limited to diagnostic products that detect nucleic acids, for example DNA or RNA. Under the agreement, Abbott Laboratories and Celera Diagnostics are obligated to work exclusively with each other in the commercialization of nucleic acid diagnostic products, except for specific products that the parties mutually agree to exclude from the alliance, if any. Diagnostic products based on the detection of proteins, rather than nucleic acids, is another potential business area for Celera Diagnostics but is not a part of the agreement with Abbott Laboratories.

Under the Abbott Laboratories agreement, Celera Diagnostics and Abbott Laboratories will jointly fund their separate but coordinated research and development activities that are within the scope of the alliance. Generally, Abbott Laboratories will market products developed and manufactured by the parties that are covered by the alliance. Celera Diagnostics believes that Abbott Laboratories expertise in the diagnostics industry and its global distribution system will enhance Celera Diagnostics ability to bring products to market. Our alliance with Abbott Laboratories, including the economic arrangements, covers all nucleic acid diagnostic products marketed by Abbott Laboratories, including any of those products manufactured by other companies.

Celera Diagnostics expects to rely substantially on its alliance with Abbott Laboratories for the success of its business strategy for the foreseeable future. Although this is a long-term alliance, the alliance agreement contains provisions that could result in early termination for reasons that include the following: breach by either company; a change in control of either company; either company s dissatisfaction with the performance of the alliance according to specific timelines for such judgments set forth in the alliance agreement; or by either company if the other party fails to meet performance criteria applicable to the other party set forth in the alliance agreement. Also, Celera Diagnostics cannot ensure that Abbott Laboratories will perform its obligations as expected. If Abbott Laboratories terminates the alliance or otherwise fails to conduct its collaborative activities in a timely manner, Celera Diagnostics development or commercialization of diagnostics products may be delayed or otherwise adversely affected.

Information about the marketing and distribution aspects of this strategic alliance is described below in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Marketing and Distribution.

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Research and Development

Overview. During our 2002 fiscal year, Celera Diagnostics first full fiscal year of operations, Celera Diagnostics focused its activities on staffing and completing its high-volume discovery laboratories, and then began research and development for products that detect infectious diseases and human genetic disorders. During our 2003 fiscal year, Celera Diagnostics substantially expanded its research and development efforts, initiating nine large-scale studies. During our 2004 fiscal year, Celera Diagnostics continued expanding its research and development activities, including advancement of its original studies and addition of new studies. In performing these studies, Celera Diagnostics is seeking to leverage its genotyping and gene expression capabilities with the SNP data from the Applera Genomics Initiative.

Celera Diagnostics is currently conducting gene-disease association studies in the following areas: Alzheimer s disease; autoimmune and inflammatory diseases, including rheumatoid arthritis; breast cancer; heart disease; liver disease; and diabetes. Most of these studies involve the analysis of large numbers of samples from healthy and diseased individuals, while a smaller number of these studies involve analysis of large numbers of samples from only diseased individuals. The goal of most of these studies is to identify SNPs that serve as genetic markers for a specific disease. In the breast cancer study, the goal is to identify gene expression patterns associated with breast cancer metastasis, which refers to the transmission of cancer cells from their original site to other sites within the body. In addition, Celera Diagnostics is conducting host response studies of SNPs and gene expression patterns in cells from patients infected with the Hepatitis C virus and patients with heart disease. The goal of these studies is to identify responsiveness to one or more forms of treatment.

During our 2004 fiscal year, Celera Diagnostics continued to advance its large-scale studies. They are all ongoing and are at different stages of progression. In the case of the Alzheimer s disease study, Celera diagnostics is continuing its research pursuant to the collaboration with Merck & Co., Inc. described above in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Development of Diagnostics Business. A key aspect of Celera Diagnostics disease study program is to seek validation of results through replication by repeating its analysis on a second population of human tissue and blood samples after the initial analysis is completed. In several studies, Celera Diagnostics has replicated results for particular markers associated with increased risk for disease that it had previously identified. Celera Diagnostics, working in cooperation with Celera Genomics, is evaluating the diagnostic and therapeutic value of the novel markers and potential therapeutic targets found, and is discussing the findings with collaborators, preparing product plans, and making patent filings to seek legal protection for its rights in the new information it has discovered.

Celera Diagnostics and Abbott Laboratories maintain separate research and development organizations and each is pursuing the development of molecular diagnostic products to be manufactured and marketed by their alliance. However, they coordinate their ongoing research and development activities, which coordination includes the sharing of scientific results and collaboration regarding the technology and instrumentation that their alliance products will use. The alliance agreement with Abbott Laboratories permits Celera Diagnostics to form collaborations and relationships with other companies to support its research activities.

Research and development expenses for Celera Diagnostics totaled $39.0 million in our 2002 fiscal year, $49.0 million in our 2003 fiscal year, and $43.8 million in our 2004 fiscal year.

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Applera expensed $381.9 million in our 2002 fiscal year, $401.5 million in our 2003 fiscal year, and $377.1 million in our 2004 fiscal year for Applera research, development, and engineering activities.

Collaborations and Other Relationships Supporting Research. Since the beginning of our 2004 fiscal year, Celera Diagnostics has entered into several new research collaboration agreements, including with Merck & Co., Inc. and with General Electric Company. These agreements are described above in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Development of Diagnostics Business.

Also, Celera Diagnostics has entered into collaboration, research, and material transfer agreements with more than 20 other companies and academic institutions to support its large-scale gene-disease association and host response studies, including ongoing studies as well as studies Celera Diagnostics plans to conduct in the future. Through these relationships, Celera Diagnostics has gained access to over 45,000 samples from human subjects. Following is a description of these relationships that Celera Diagnostics has publicly announced:

- an agreement with Bristol-Myers Squibb Company to study genes that may be useful in the diagnosis and treatment of heart disease and diabetes;

- a research initiative with the University of California, San Francisco, Comprehensive Cancer Center to develop new diagnostic tools for breast cancer; and

- an agreement with Genomics Collaborative, Inc. to support Celera Diagnostics efforts to identify genetic patterns associated with rheumatoid arthritis.

Product Development Collaborations. If Celera Diagnostics gene-disease association studies are successful, Celera Diagnostics expects to develop and market reagents that detect the newly discovered genetic markers. Celera Diagnostics has entered into the following research collaborations to support its efforts to develop these products:

- a collaboration with Quest Diagnostics Incorporated to establish the clinical utility of laboratory tests based on novel diagnostic markers for heart disease and diabetes; and

- a collaboration with Laboratory Corporation of America Holdings to establish the clinical utility of laboratory tests based on novel diagnostic markers for Alzheimer s disease, breast cancer, and prostate cancer.

Celera Diagnostics Products

Celera Diagnostics plans to develop products that provide useful genetic information to facilitate disease detection, prediction of disease predisposition, monitoring of disease progression, and disease severity, and determination of patient responsiveness to treatments. These products are expected to include *in vitro* diagnostic test kits, which may be labeled for use in diagnosing specific diseases or other conditions, as well as products referred to as analyte specific reagents, which may be used by appropriately-licensed clinical laboratories for clinical laboratory testing after they independently establish the performance characteristics of the

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reagents but which may not be labeled by Celera Diagnostics for use in diagnosing any specific disease or condition.

While the sale of *in vitro* diagnostic test kits requires clearance or approval by the FDA, analyte specific reagents are a class of products defined by the agency s regulations which may be sold without any regulatory submission. However, analyte specific reagents must be manufactured and marketed in compliance with the requirements of the agency s Quality System Regulations, such as Good Manufacturing Practices, and must be sold in compliance with FDA regulations regarding their sale, distribution, and use. These FDA regulations are intended to ensure, among other things, that purchasers are aware that the utilities and performance characteristics of these products have not been established. Because analyte specific reagents are not subject to FDA clearance or approval, Celera Diagnostics believes they can generally be commercialized sooner than diagnostic test kits. However, the regulatory restrictions on the marketing, distribution, and sale of analyte specific reagents, and on its customers use of these products, would likely affect their marketing and distribution and market acceptance.

Celera Diagnostics is currently offering five products through its alliance with Abbott Laboratories, which is described above in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Abbott Laboratories Strategic Alliance and below in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Marketing and Distribution. Celera Diagnostics is manufacturing all of these products, and except as noted below they are marketed and distributed by Abbott Laboratories.

ViroSeq HIV-1 Genotyping System. The genome of human immunodeficiency virus, commonly known as HIV, undergoes mutations in an infected patient, especially in response to anti-viral drug treatment. Some of the mutations have been shown to render the virus resistant to the action of some drugs, thereby diminishing the effectiveness of the treatment. Therefore, the detection of mutations in HIV that correlate with drug resistance provides useful information to physicians in monitoring the course of treatment and selecting the most effective regimen for each individual HIV-infected patient.

Celera Diagnostics ViroSeq HIV-1 Genotyping System was developed as an aid to physicians in monitoring and treating HIV-1 infection. HIV-1 is one of the most prevalent strains of HIV. This system is for use in testing human blood samples and was designed to detect specific mutations in the HIV-1 genome that correlate with drug resistance. The product includes reagents for identifying key mutations of the HIV-1 genome designed for use on an Applied Biosystems automated DNA sequencing instrument in conjunction with Celera Diagnostics ViroSeq® HIV-1 Genotyping System Software. The system currently can be used to test for resistance to up to 19 drugs used to treat HIV-1 infected patients, including the four drugs covered by the February 2004 FDA clearance described in the following paragraph.

Through its alliance with Abbott Laboratories, Celera Diagnostics is marketing the system in the U.S. and the European Union. During our 2002 and 2003 fiscal years, Celera Diagnostics submitted three 510(k) filings to the FDA for the ViroSeq HIV-1 Genotyping System. A 510(k) filing is a pre-market notification to the FDA that Celera Diagnostics intends to market this product as an *in vitro* diagnostic test kit. The product could not be marketed in the U.S. until the FDA provided clearance.

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During our 2003 fiscal year, the FDA granted marketing clearances for the system for use on the Applied Biosystems ABI PRISM® 377 DNA Sequencer, 3100 Genetic Analyzer, and 3700 DNA Analyzer. In February 2004, the FDA granted a clearance for expanded claims, clearing the use of the system on the 3100 Genetic Analyzer and the 3700 DNA Analyzer to test for resistance to four additional drugs used to treat HIV-1 infected patients. The model 377, 3100, and 3700 instruments are discussed above in Item 1 of this report under the headings Applied Biosystems Group Business Products for the Genomics Market Genetic Analysis Instruments; Genotyping and Resequencing Systems.

During our 2004 fiscal year, Celera Diagnostics received its CE mark registration of the ViroSeq HIV-1 Genotyping System for use on the ABI PRISM 3100 Genetic Analyzer for marketing in the EU. The system had previously been marketed in several other jurisdictions for research use purposes only, which does not require regulatory clearance or approval. However, this research use only version of the ViroSeq system was discontinued during our 2004 fiscal year.

Additional information regarding the regulation of Celera Diagnostics products is set forth below in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Regulation of Diagnostic Products.

Cystic Fibrosis Analyte Specific Reagents. Cystic fibrosis is an inherited genetic disorder that affects children and young adults. It is caused by a number of mutations in the cystic fibrosis gene. The American College of Obstetricians and Gynecologists currently recommends that couples planning a pregnancy or seeking prenatal care be screened for cystic fibrosis gene mutations to help them make informed reproductive decisions. Celera Diagnostics sells analyte specific reagents that can be used by appropriately licensed clinical laboratories to identify mutations in the cystic fibrosis gene. Laboratories using the reagents for this purpose must first independently establish the performance characteristics of any test they develop using Celera Diagnostics analyte specific reagents.

HLA Sequencing-Based Typing Kits. Transplantation of tissues and organs between genetically-unrelated individuals usually results in rejection of the donor graft, or tissue, by the recipient. Such rejection is due to differences in some genes between a donor and a recipient. These genes have been mapped to a region of the human genome known as HLA. Analysis of HLA genes to match donor-recipient pairs with minimal differences in these genes has greatly improved the success of transplantation.

Celera Diagnostics HLA-typing products detect specific DNA sequences in several HLA genes that are known to be involved in transplantation rejection, and thus provide useful information regarding the likelihood of transplant rejection by a recipient. Celera Diagnostics has not sought or received marketing clearance or regulatory approval from the FDA for these products, and does not manufacture these products in accordance with FDA requirements. Accordingly, these products can be sold only for research use and cannot be sold for diagnostic purposes either as diagnostic kits or as analyte specific reagents. Although these products are covered by the Abbott Laboratories alliance, currently Celera Diagnostics is responsible for

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sales and marketing in the U.S. because Abbott Laboratories does not specialize in the sale of products to the research market.

Celera Diagnostics intends to discontinue the sale of these products during our 2005 fiscal year, and Abbott Laboratories has contributed a different HLA-typing product to the alliance to replace this product.

Hepatitis C Virus Analyte Specific Reagents. Hepatitis C virus causes a chronic liver disease. Hepatitis C virus infection is currently the leading reason that patients need liver transplants. There are several distinct strains of Hepatitis C virus having different genotypes, and some of these genotypes are more susceptible to currently-available treatments than others. Celera Diagnostics manufactures two analyte specific reagent products for Abbott Laboratories for Hepatitis C virus. One of these products can be used to measure viral load, which refers to the quantity of the virus found in a tissue sample. The other product can be used to identify the genotypes of the different strains of the Hepatitis C virus. Only appropriately-licensed clinical laboratories can use these analyte specific reagents for these purposes after they independently establish the performance characteristics of any test they develop using Celera Diagnostics analyte specific reagents.

In addition to the products described above, Celera Diagnostics performs contract manufacturing and technology development services in collaboration with appropriately licensed clinical laboratories. These services are for the development and manufacture of reagents for use by the clinical laboratories in the performance of clinical testing services. Some of these contract manufacturing and technology development services fall outside of Celera Diagnostics alliance with Abbott Laboratories.

Also, Abbott Laboratories is currently marketing several other nucleic acid diagnostic products that are being manufactured by other companies. Our alliance with Abbott Laboratories, including the economic arrangements, covers all nucleic acid diagnostic products marketed by Abbott Laboratories, including these products.

Regulation of Diagnostic Products

In the U.S. and in other countries, diagnostic products are heavily regulated by governmental agencies. These requirements vary from country to country. Currently, Celera Diagnostics principal markets are the U.S. and the European Union, and the regulatory requirements in those jurisdictions are described below.

In the U.S., the FDA classifies Celera Diagnostics *in vitro* diagnostic products as devices and the FDA s Center for Devices and Radiological Health regulates these products. Although some of the products that Celera Diagnostics expects to market may not require regulatory clearance or approval, its current business strategy is to develop and market a number of products that will be devices and require this clearance or approval. For Celera Diagnostics to market its *in vitro* diagnostic products with clinical claims in the U.S., Celera Diagnostics or its collaborators generally must first obtain clearance from the FDA pursuant to a process known as 510(k) premarket notification, or must obtain FDA approval through a more demanding premarket approval, or PMA, process.

In order to obtain a 510(k) premarketing clearance, which refers to Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FFDCA, Celera Diagnostics or its collaborators

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generally must file a notice with the FDA with clinical data demonstrating that the device subject to the notification and its intended purpose are substantially equivalent to a diagnostic device that is already cleared or approved for marketing by the FDA. The 510(k) clearance process usually takes from three to twelve months, but can take longer. For example, the FDA may require further information, including additional clinical data, to make a determination regarding substantial equivalence to a legally marketed device. Celera Diagnostics has successfully applied for and received 510(k) clearances for its ViroSeq HIV-1 Genotyping System, and a description of the clearances it has received is set forth above in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Celera Diagnostics Products. From time to time, we may publicly refer to special 510(k) clearances from the FDA. A special 510(k) clearance is an alternative to the traditional 510(k) method of premarket notification. It is the least burdensome mechanism for reporting significant modifications to a previously cleared diagnostic device and can be used when the modifications do not change the intended use of the previously cleared diagnostic device.

If the substantially equivalent standard is not met for a 510(k) premarketing clearance, a PMA application must be filed pursuant to the FFDCA. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that a device is safe and effective, must be supported by more extensive information than required for a 510(k) notification. The PMA application process is more costly, lengthy, and uncertain and usually takes one to three years, but can take longer.

Following FDA clearance or approval of a device allowing its commercial distribution, numerous regulatory requirements apply, including: the Quality System Regulations, which require manufacturers to follow elaborate design, testing, control, documentation, and other quality assurance procedures during the manufacturing process; labeling regulations; and the Medical Device Reporting regulation, which requires that the manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur.

Failure to comply with the applicable U.S. regulatory requirements for *in vitro* diagnostic products could result in, among other things, warning letters, fines, injunctions, civil penalties, recalls, or seizure of products, total or partial suspension of production, the FDA s refusal to grant future premarket clearances or approvals, withdrawals of current product applications, and criminal prosecution.

In addition, distribution and sale of all diagnostic products in the European Union are subject to regulatory requirements that became effective on December 7, 2003. Pursuant to these requirements, Celera Diagnostics *in vitro* diagnostic products exported to the EU must comply with the In Vitro Diagnostics Directive and bear the CE mark. The Directive describes criteria that must be met and steps that must be taken for *in vitro* diagnostic products to be qualified for sale in EU countries. The CE mark is a symbol indicating that products conform to the essential requirements of the Directive, and can be commercially distributed throughout the EU. In order to demonstrate compliance, Celera Diagnostics is required to either self-certify or provide documented evidence to a certification organization referred to as a Notified Body that the products to be marketed meet all of the applicable essential requirements. Once Celera Diagnostics has satisfied the compliance requirements, the CE mark may be affixed on the products concerned. However, in order to maintain use of the CE mark for some products, Celera Diagnostics will be subject to continuing review by the Notified Body, if applicable.

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During our 2004 fiscal year, Celera Diagnostics received CE mark registration for its ViroSeq HIV-1 Genotyping System for use on the ABI PRISM 3100 Genetic Analyzer, and is in the process of completing, or intends to prepare, required documentation for CE mark registration for some of its other products. However, Celera Diagnostics cannot assure that the CE mark registration will be granted for Celera Diagnostics other products or that it will maintain its compliance with these requirements. Celera Diagnostics failure to meet these requirements may prevent it from generating revenue from the sale of diagnostic products in the EU.

Marketing and Distribution

Celera Diagnostics expects that reference laboratories, hospitals, and medical clinics that perform diagnostic testing will be the primary users of its products. Celera Diagnostics does not expect to develop its own marketing and distribution organization for the foreseeable future. Under the terms of its strategic alliance with Abbott Laboratories, Abbott Laboratories will serve as Celera Diagnostics exclusive worldwide distributor of nucleic acid-based diagnostic products developed under the agreement. The Abbott Laboratories alliance agreement is discussed above in Item 1 of this report under the headings Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics Abbott Laboratories Strategic Alliance.

Pursuant to the Abbott Laboratories strategic alliance, on October 1, 2002, Abbott Laboratories commenced the marketing, distribution, and end-user sale of most existing Celera Diagnostic products. Celera Diagnostics expects that most of its nucleic acid testing products for the foreseeable future will be covered by the Abbott Laboratories agreement so long as it remains in effect and will be marketed, distributed, and sold through Abbott Laboratories. However, Celera Diagnostics may develop products not covered by the agreement, in which case Celera Diagnostics would have to develop its own marketing and distribution capability or find other distributors for these products.

Raw Materials

Celera Diagnostics operations require a variety of raw materials, such as chemical and biochemical materials, and other supplies, some of which are occasionally found to be in short supply. Any interruption in the availability of these materials could adversely affect Celera Diagnostics operations.

In particular, Celera Diagnostics needs access to human tissue and blood samples from diseased and healthy individuals, other biological materials, and related clinical and other information, which may be in limited supply. Celera Diagnostics may not be able to obtain or maintain access to these materials and information on acceptable terms, or may not be able to obtain needed consents from individuals providing tissue or blood samples. In addition, government regulation in the U.S. and foreign countries could result in restricted access to, or use of, human tissue or blood samples. If Celera Diagnostics loses access to sufficient numbers or sources of tissue or blood samples, or if tighter restrictions are imposed on its use of the information generated from tissue or blood samples, its business may be harmed.

Patents, Licenses, and Franchises

Through its internal research programs and collaborative programs, including the Applera Genomics Initiative, Celera Diagnostics anticipates that it will develop an increasing

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portfolio of intellectual property. Celera Diagnostics may use such intellectual property in its internal development programs or may license it to third parties or customers for some combination of license fees, milestone payments, and royalty payments.

Celera Diagnostics products are based on complex, rapidly developing technologies. Some of these technologies are covered by patents owned by Applied Biosystems and Celera Genomics, and other patents are owned by third parties and used by Celera Diagnostics under license.

In addition, Celera Diagnostics alliance with Abbott Laboratories provides Celera Diagnostics with rights to some intellectual property owned or licensed by Abbott Laboratories that Celera Diagnostics needs for its business and products.

Competition

The diagnostics industry in which Celera Diagnostics operates is competitive and evolving. There is intense competition among healthcare, biotechnology, and diagnostic companies attempting to discover candidates for potential new diagnostic products. These companies may:

develop new diagnostic products in advance of Celera Diagnostics or its collaborators;

develop diagnostic products which are more effective or more cost-effective than those developed by Celera Diagnostics or its collaborators;

obtain regulatory clearance or approval of their diagnostic products more rapidly than Celera Diagnostics or its collaborators; or

obtain patent protection or other intellectual property rights that would limit Celera Diagnostics or its collaborators ability to develop and commercialize, or their customers ability to use, Celera Diagnostics and its collaborators diagnostic products.

Celera Diagnostics competes with companies in the U.S. and abroad that are engaged in the development and commercialization of products and services that provide genetic information. These companies may develop products that are competitive with the products offered by Celera Diagnostics or its collaborators, such as analyte specific reagents or diagnostic test kits that perform the same or similar purposes as Celera Diagnostics or its collaborators products. Also, clinical laboratories may offer testing services that are competitive with the products sold by Celera Diagnostics or its collaborators. For example, a clinical laboratory can use either reagents purchased from manufacturers other than Celera Diagnostics, or use its own internally developed reagents, to make diagnostic tests. If clinical laboratories make tests in this manner for a particular disease, they could offer testing services for that disease as an alternative to products sold by Celera Diagnostics used to test for the same disease. The testing services offered by clinical laboratories may be easier to develop and market than test kits developed by Celera Diagnostics or its collaborators because the testing services are not subject to the same clinical validation requirements that are applicable to FDA-cleared or approved diagnostic test kits. The diagnostic testing services market is dominated by a small number of large clinical

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testing laboratories, including Laboratory Corporation of America Holdings, Quest Diagnostics Inc., and Specialty Laboratories, Inc.

Also, a substantial portion of all sales of diagnostic products are made to a small number of clinical reference laboratories, including those identified above, and therefore Celera Diagnostics expects to rely on these laboratories for a substantial portion of its sales. Celera Diagnostics inability to establish or maintain one or more of these laboratories as a customer could adversely affect its business, financial condition, and operating results.

Environmental Matters

Celera Diagnostics is subject to federal, state, and local laws and regulations regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, in those jurisdictions where Celera Diagnostics operates or maintains facilities. Celera Diagnostics does not believe that any liability arising under, or compliance with, environmental laws or regulations will have a material effect on its business, and no material capital expenditures are expected for environmental control.

Applera Genomics Initiative

In July 2001, we announced a collaboration among Celera Genomics, Applied Biosystems, and Celera Diagnostics for commercializing products derived from information obtained through analysis of variations in the human genome. This collaboration, which we refer to as the Applera Genomics Initiative, was commenced primarily to develop a portfolio of validated SNPs to be used as the basis for these products. The Applera Genomics Initiative was completed during our 2003 fiscal year and was jointly funded by all three business segments.

Pursuant to the Applera Genomics Initiative, Celera Genomics prioritized and resequenced approximately 25,000 genes from 39 individuals and a chimpanzee. From this resequencing, Celera Genomics identified over 294,000 SNPs in genes, of which we believe approximately 75% are novel SNPs not previously identified by other researchers. Based on our analysis of the location of these SNPs on the human genome, we believe that over 45,000 of the novel SNPs could affect the amount, stability, or function of proteins. SNPs that have these properties are referred to as functional SNPs and may have the greatest biological and medical value. The Applera Genomics Initiative also included Applied Biosystems SNP validation studies. SNP validation was performed to confirm that publicly available SNPs are true genetic variations rather than sequencing errors, and to determine the frequency of SNPs across multiple racial and ethnic populations to confirm their utility in life science research.

We believe the SNP information that we have generated through the Applera Genomics Initiative will be an important asset for all three of our business segments. Applied Biosystems is incorporating the SNP data into new SNP assay products for the research market. Celera Diagnostics is using this information in disease association studies aimed at identifying new diagnostic markers. Celera Genomics is using the SNP information in its proteomics discovery efforts and may also benefit from therapeutic implications of findings from the disease association studies.

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Employees

As of June 30, 2004, we had approximately 5,360 employees allocated as follows:

Business/Function	Number
Applied Biosystems	4,400
Celera Genomics	530
Celera Diagnostics	220
Corporate Staff	210

Our corporate staff provides accounting, tax, treasury, legal, information technology, human resources, and other internal services for Applied Biosystems, Celera Genomics, and Celera Diagnostics. None of Applied Biosystems U.S. employees, and none of Celera Genomics or Celera Diagnostics employees or our corporate staff employees, are subject to collective bargaining agreements. We generally consider our relations with our employees to be good.

Financial Information About Industry Segments

A summary of net revenues from external customers and operating income (loss) attributable to each of our industry segments for our fiscal years ended June 30, 2002, 2003, and 2004, is incorporated herein by reference to Note 15 on pages 73 through 85 of our 2004 Annual Report. Total assets as of June 30, 2002, 2003, and 2004 were as follows:

June 30, 2002: $1,818.6 million for Applied Biosystems, $1,250.0 million for Celera Genomics, $21.8 million for Celera Diagnostics, and $3,075.4 million for Applera after the effects of ($15.0) million related to intercompany eliminations;

June 30, 2003: $2,126.7 million for Applied Biosystems, $1,122.1 million for Celera Genomics, $35.9 million for Celera Diagnostics, and $3,257.5 million for Applera after the effects of ($27.2) million related to intercompany eliminations; and

June 30, 2004, were $1,947.8 million for Applied Biosystems, $1,017.7 million for Celera Genomics, $36.9 million for Celera Diagnostics, and $2,972.9 million for Applera after the effects of ($29.5) million related to intercompany eliminations.

Celera Diagnostics was first presented as a segment during our 2002 fiscal year.

Financial Information About Geographic Areas

A summary of net revenues from external customers and long-lived assets attributed to each of our geographic areas for our 2002, 2003, and 2004 fiscal years is incorporated herein by reference to Note 15 on pages 73 through 85 of our 2004 Annual Report.

Our consolidated net revenues from external customers in countries other than the U.S. for our 2002, 2003, and 2004 fiscal years were as follows:

$878.6 million, or 51.6% of our consolidated net revenues, for our 2002 fiscal year;

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$891.3 million, or 50.2% of our consolidated net revenues, for our 2003 fiscal year; and

$956.7 million, or 52.4% of our consolidated net revenues, for our 2004 fiscal year.

Our manufacturing facilities outside the continental U.S. are located in the United Kingdom, Japan, and Singapore.

Executive Officers of the Registrant

Information concerning our executive officers is incorporated by reference to the description in Part III, Item 10 of this report under the heading Identification and Business Experience of Executive Officers on pages 94 and 95 of this report.

Item 2. Properties

Applied Biosystems Group Facilities

Applied Biosystems headquarters are located in leased facilities in Foster City, California. Applied Biosystems owns or leases various other facilities worldwide for manufacturing, distribution, warehousing, research and development, sales and demonstration, service, and administration. The following is a list of Applied Biosystems principal and other material operating facilities. Except as otherwise noted below, substantially all of the space in these facilities is used by Applied Biosystems, and these facilities are maintained in good working order. This table does not reflect facilities that are leased by Applied Biosystems, or unused space in facilities leased by Applied Biosystems, that Applied Biosystems is seeking to sublease.

Location (Approximate Floor Area in Sq. Ft.)	Owned or Leased (Expiration Date of Leases)
Foster City, CA (655,000) several buildings	Leased (several leases expiring 2004-2015)
Hayward, CA (66,000)	Leased (2009)
Pleasanton, CA (149,000) three buildings	Owned
San Jose, CA (81,000)	Owned
Bedford, MA (104,000) four buildings	Leased (several leases expiring 2004, 2007, 2011, and 2023)
Framingham, MA (140,000)	Leased (2009)
Houston, TX (50,000)	Leased (2009)
Warrington, United Kingdom (88,000) two buildings	Owned
Rotterdam, Netherlands (64,000)	Leased (2010)
Singapore (45,000)	Leased (several leases expiring 2005-2006)
Narita, Japan (24,000)	Owned

Applied Biosystems purchased an 80-acre property in Pleasanton, California, in September 2000 on which it could construct facilities of up to 960,000 square feet. Applied Biosystems currently intends to construct new facilities on this property with up to approximately 600,000 square feet for research and development, manufacturing, and administrative purposes as may be required by the future growth of our business. The Pleasanton facilities reflected in the table above include a manufacturing facility, as well as two additional buildings that had been erected to support construction but which Applied Biosystems is currently using for maintenance and warehousing. Applied Biosystems has also completed construction of the shell of a building at the same site comprised of approximately 164,000

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square feet. Applied Biosystems intends to construct improvements needed for occupancy in this building as additional space is needed for its operations or possibly the operations of our other businesses.

Applied Biosystems also owns approximately 15 acres of undeveloped land in Vacaville, California.

Celera Genomics Group Facilities

Celera Genomics business is primarily located in owned facilities in Rockville, Maryland, and leased and owned facilities in South San Francisco, California. The Rockville facilities are used for administrative purposes and to house Celera Genomics bioinformatics data center and proteomics laboratory. The South San Francisco facilities contain Celera Genomics therapeutic discovery and development operations and administrative offices. The following is a list of Celera Genomics principal and other material operating facilities. Except as otherwise noted below, substantially all of the space in these facilities is used by Celera Genomics, and these facilities are maintained in good working order.

Location (Approximate Floor Area in Sq. ft.)	**Owned or Leased (Expiration Date of Leases)**
Rockville, MD (220,000) two buildings	Owned
South San Francisco, CA (70,000)	Leased (2006)
South San Francisco, CA (44,000)	Owned
South San Francisco, CA (14,000)	Leased (2006)
South San Francisco, CA (24,000)	Leased (2006)

Celera Genomics is using approximately 75% of the space in Rockville, Maryland. The Rockville facilities are located on a parcel of land we own that includes approximately 5 undeveloped acres that are suitable for development. Celera Genomics is seeking to sell this property, and intends to either lease back needed space after any sale or lease facilities in a nearby location depending on the terms of any sale that may occur.

Celera Genomics also leases an 85,000 square foot facility in Pasadena, California. Celera Genomics has vacated most of the space in this facility and a portion of the vacated space has been subleased. Celera Genomics is evaluating its alternatives for the remaining vacated space until the expiration of the lease in 2011.

The owned facility in South San Francisco, California, is located on land we lease under a long-term ground lease.

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Celera Diagnostics Facilities

We have leased the following three facilities to serve as the principal facilities for Celera Diagnostics, which Celera Diagnostics is using as its headquarters as well as for research and development, manufacturing, and administrative purposes. These facilities are maintained in good working order.

Location (Approximate Floor Area in Sq. Ft.)	Owned or Leased (Expiration Date of Leases)
Alameda, CA (48,000)	Leased (2006)
Alameda, CA (19,000)	Leased (2006)
Alameda, CA (8,000)	Leased (2006)

Celera Diagnostics is using all of the space in the first facility listed above. Celera Diagnostics is using all of the space in the second facility listed above, but the building containing this facility includes approximately 9,000 more square feet of space that is currently occupied by a sub-tenant and which Celera Diagnostics intends to occupy during the 2005 fiscal year after the sub-tenant leaves the space. The space in the third facility listed above is a portion of a 32,000 square foot facility that was vacated by a defaulting subtenant and occupied by Celera Diagnostics.

Corporate Facilities

Our corporate headquarters is located in a facility in Norwalk, Connecticut, under a lease that expires in 2011. We lease approximately 51,000 square feet at this facility, substantially all of which we use for corporate staff and related support functions. This facility is maintained in good working order.

We also own another facility in Norwalk and Wilton, Connecticut, with an area of approximately 402,000 square feet. This facility was previously used for our corporate headquarters and manufacturing, but is currently vacant. We are holding this facility for sale or long term lease. This facility is expected to remain vacant pending completion of such a sale or lease.

Item 3. Legal Proceedings

We are involved in various legal proceedings from time to time, including actions with respect to commercial, intellectual property, antitrust, environmental, securities, and employment matters. The following is a description of some claims we are currently defending. We believe that we have meritorious defenses against the claims currently asserted against us, including those described below, and intend to defend them vigorously. However, the outcome of litigation is inherently uncertain, and we cannot be sure that we will prevail in any of the cases described below or in our other current litigation. An adverse determination in some of our current litigation, particularly the cases described below under the headings Securities Litigation, MJ Research and Henry Huang, Promega, Beckman Coulter, Genetic Technologies, On-Line Technolog Roche, Enzo Biochem, and Bio-Rad could have a material adverse effect on us.

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U.S. v. Davis

We are a party to the action U.S. v. Davis, pending in the U.S. District Court for the District of Rhode Island. We were brought into the case along with numerous other companies as a result of a third party complaint filed by United Technologies Corporation (UTC) seeking contribution for environmental cleanup costs imposed by the U.S. government. In December 1998, the District Court found us liable to UTC along with certain, but not all, of the defendants in the case. We believe the amount of such liability to be less than $200,000, which will be determined when all appeals have been concluded. Both UTC and we appealed the District Court s decision. In August 2001, the U.S. Court of Appeals for the First Circuit affirmed the District Court s decision and remanded the case to the District Court for further proceedings.

Securities Litigation

Our company and some of our officers were served in five lawsuits between April and May, 2000, purportedly on behalf of purchasers of Applera-Celera stock in our follow-on public offering of Applera-Celera stock completed on March 6, 2000. In the offering, we sold an aggregate of approximately 4.4 million shares of Applera-Celera stock at a public offering price of $225 per share. All of these lawsuits have been consolidated into a single case and are pending in the U.S. District Court for the District of Connecticut, and an amended consolidated complaint was filed on August 21, 2001. The consolidated complaint generally alleges that the prospectus used in connection with the offering was inaccurate or misleading because it failed to adequately disclose the alleged opposition of the Human Genome Project and two of its supporters, the governments of the U.S. and the U.K., to providing patent protection to our genomic-based products. Although Celera Genomics has never sought, or intended to seek, a patent on the basic human genome sequence data, the complaint also alleges that we did not adequately disclose the risk that Celera Genomics would not be able to patent this data. The consolidated complaint seeks monetary damages, rescission, costs and expenses, and other relief as the court deems proper.

MJ Research and Henry Huang

We are involved in several litigation matters with MJ Research, Inc., which commenced with our filing claims against MJ Research based on its alleged infringement of some polymerase chain reaction, or PCR, patents. In response to our claims, MJ Research filed counterclaims including, among others, allegations that we have licensed and enforced these patents through anticompetitive conduct in violation of federal and state antitrust laws, and MJ Research is seeking injunctive relief, monetary damages, costs and expenses, and other relief. A trial on these matters commenced in March 2004. The court elected to hold the trial in two phases: a patent phase and an antitrust phase. In the patent phase, which has concluded, the jury found that MJ Research infringed U.S. Patent Nos. 4,683,195, 4,683,202 and 4,965,188 (each relates to PCR process technology) and U.S. Patent Nos. 5,656,493, 5,333,675 and 5,475,610 (each relates to thermal cycler instrument technology). The jury found the infringement of the 195, 202, 188 and 493 patents to be willful. In addition to direct infringement by MJ Research of the 610 and 675 patents, the jury found that MJ Research induced its customers to infringe all of the patents and contributed to infringement by its customers of the 610 and 675 patents. In April 2004, the jury awarded damages to us and Roche Molecular Systems, also a party to the litigation, in the amount of $19.8 million. We intend to seek, with Roche Molecular Systems, an enhancement of damages, including legal fees, since several infringements were found to be willful. Additionally,

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we intend to seek an injunction against MJ Research, which filed for bankruptcy court protection on March 29, 2004. The antitrust phase of the trial has not yet commenced.

Subsequent to the filing of our claims against MJ Research which are described in the preceding paragraph, on September 21, 2000, MJ Research filed an action against us in the U.S. District Court for the District of Columbia. This complaint is based on the allegation that the patents underlying our DNA sequencing instruments were improperly obtained because one of the alleged inventors, whose work was funded in part by the U.S. government, was knowingly omitted from the patent applications. Our patents at issue are U.S. Patent Nos. 5,171,534, entitled Automated DNA Sequencing Technique, 5,821,058, entitled Automated DNA Sequencing Technique, 6,200,748, entitled Tagged Extendable Primers and Extension Products, and 4,811,218, entitled Real Time Scanning Electrophoresis Apparatus for DNA Sequencing. The complaint asserts violations of the federal False Claims Act and the federal Bayh Dole Act, invalidity and unenforceability of the patents at issue, patent infringement, and various other civil claims against us. MJ Research is seeking monetary damages, costs and expenses, injunctive relief, transfer of ownership of the patents in dispute, and other relief as the court deems proper. MJ Research claims to be suing in the name of the U.S. government although the government has to date declined to participate in the suit. On October 9, 2003, the case against us was dismissed but MJ Research has filed an appeal.

Henry Huang (an individual) filed an action against us and Applied Biosystems and the other parties described below in the U.S. District Court for the Central District of California on February 19, 2003. Mr. Huang s complaint seeks to change inventorship of the patents described below, and claims breach of contract, fraud, conversion, and unjust enrichment. The complaint relates to U.S. Patent Nos. 5,171,534, entitled Automated DNA Sequencing Technique, 5,821,058, entitled Automated DNA Sequencing Technique, 6,200,748, entitled Tagged Extendable Primers and Extension Products, and 4,811,218, entitled Real Time Scanning Electrophoresis Apparatus for DNA Sequencing. U.S. Patent Nos. 5,171,534, 5,821,058, and 6,200,748 are assigned to the California Institute of Technology and licensed by Applied Biosystems. U.S. Patent No. 4,811,218 is assigned to Applied Biosystems. Also named in the complaint are the California Institute of Technology, Lloyd Smith, Leroy Hood, Michael Hunkapiller, Timothy Hunkapiller, Charles Connell, John Lytle, William Mordan, and John Bridgham. Lloyd Smith, Leroy Hood, Michael Hunkapiller, Timothy Hunkapiller, and Charles Connell are the inventors named on U.S. Patent Nos. 5,171,534, 5,821,058, and 6,200,748. Michael Hunkapiller, Charles Connell, John Lytle, William Mordan, and John Bridgham are the inventors named on U.S. Patent No. 4,811,218. The issues involved in this litigation are related to the issues in the MJ Research, Inc. litigation that was filed September 21, 2000, which is described above. Mr. Huang is alleging that he is the sole inventor on U.S. Patent Nos. 5,171,534, 5,821,058, 6,200,748, and 4,811,218. He is seeking to substitute himself for the named inventors on the relevant patents, and to have himself named as the sole assignee of the patents, and is also seeking monetary damages, costs, expenses, and other relief as the court deems proper. A trial was completed on December 22, 2003, and on February 18, 2004, the judge issued a decision in our favor finding that Mr. Huang was not an inventor of the patents at issue. Mr. Huang had appealed the decision, but on July 22, 2004, he filed a stipulation with the court withdrawing his appeal, resulting in the termination of this litigation.

Promega

Promega Corporation filed a patent infringement action against Lifecodes Corporation, Cellmark Diagnostics, Genomics International Corporation, and us in the U.S. District Court for

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the Western District of Wisconsin on April 24, 2001. The complaint alleges that the defendants are infringing Promega s U.S. Patent Nos. 6,221,598 and 5,843,660, both entitled Multiplex Amplification of Short Tandem Repeat Loci, due to the defendants sale of forensic identification and paternity testing kits. Promega is seeking monetary damages, costs and expenses, injunctive relief, and other relief as the court deems proper. The defendants answered the complaint on July 9, 2001, and we asserted counterclaims alleging that Promega is infringing our U.S. Patent No. 6,200,748, entitled Tagged Extendable Primers and Extension Products, due to Promega s sale of forensic identification and paternity testing kits. As a result of settlement negotiations, the case was dismissed without prejudice on October 29, 2002, but could be re-filed against us if settlement negotiations are not successful.

Promega Corporation filed an action against us and some of our affiliates and Roche Molecular Systems, Inc. and Hoffmann-La Roche, Inc. in the U.S. District Court for the Eastern District of Virginia on April 10, 2000. The complaint asserts violations of the federal False Claims Act. On November 12, 2003, the court issued an order to have the complaint, which had previously been sealed, served on us and the other defendants. On February 9, 2004, we waived service of the complaint, which initiated our direct involvement in the case. The complaint alleges that we and Hoffmann-La Roche overcharged the U.S. government for thermal cyclers and PCR reagents. The overcharges are alleged to be the result of a licensing program based in part on U.S. Patent No. 4,889,818. Promega is asserting that U.S. Patent No. 4,889,818 was obtained fraudulently and that the licensing program run by us and Hoffmann-La Roche is the cause of the alleged overcharging. Promega is seeking monetary damages. Promega claims to be suing in the name of the U.S. government although the government has to date declined to participate in the suit. On June 29, 2004, the court granted our motion to dismiss for failure to state a claim upon which relief could be granted, but gave Promega the right to file an amended complaint. Promega filed an amended complaint on July 13, 2004, and we filed another motion to dismiss on August 6, 2004. The court granted our second motion to dismiss on August 20, 2004, but we have not yet received the written court opinion and therefore do not know the full scope of that decision.

Beckman Coulter

Beckman Coulter, Inc. filed a patent infringement action against us in the U.S. District Court for the Central District of California on July 3, 2002. The complaint alleges that we are infringing Beckman Coulter s U.S. Patent Nos. RE 37,606 and 5,421,980, both entitled Capillary Electrophoresis Using Replaceable Gels, and U.S. Patent No. 5,552,580, entitled Heated Cover Device. The allegedly infringing products are Applied Biosystems capillary electrophoresis sequencing and genetic analysis instruments, and PCR and real-time PCR systems. Since Beckman Coulter filed this claim, U.S. Patent No. 5,421,980 has been reissued as U.S. Patent No. RE 37,941, entitled Capillary Electrophoresis Using Replaceable Gels. On January 13, 2003, the court permitted Beckman Coulter to make a corresponding amendment to its complaint. Beckman Coulter is seeking monetary damages, costs and expenses, injunctive relief, and other relief as the court deems proper. On February 10, 2003, we filed our answer to Beckman Coulter s allegations, and counterclaimed for declaratory relief that the Beckman Coulter patents underlying Beckman Coulter s claim are invalid, unenforceable, and not infringed. We are seeking dismissal of Beckman Coulter s complaint, costs and expenses, declaratory and injunctive relief, and other relief as the court deems proper.

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Genetic Technologies

Genetic Technologies Limited filed a patent infringement action against us in the U.S. District Court for the Northern District of California on March 26, 2003. They filed an amended complaint against us on August 12, 2003. The amended complaint alleges that we are infringing U.S. Patent No. 5,612,179, entitled Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes, and U.S. Patent No. 5,851,762, entitled Genomic Mapping Method by Direct Haplotyping Using Intron Sequence Analysis. The allegedly infringing products are cystic fibrosis reagent kits, TaqMan® genotyping and gene expression assay products for non-coding regions, TaqMan genotyping and gene expression assay services for non-coding regions, and the Celera Discovery System™. The complaint also alleges that haplotyping analysis performed by our businesses infringes the patents identified above. Genetic Technologies Limited is seeking monetary damages, costs, expenses, injunctive relief, and other relief as the court deems proper.

On-Line Technologies

On-Line Technologies, Inc. (since acquired by MKS Instruments, Inc.) filed claims for patent infringement, trade secret misappropriation, fraud, breach of contract and unfair trade practices against PerkinElmer, Inc., Sick UPA, GmbH, and us in the U.S. District Court for the District of Connecticut on or about November 3, 1999. The complaint alleged that products called the Spectrum One and the MCS100E manufactured by former divisions of Applied Biosystems, which divisions were sold to the co-defendants in this case, were based on allegedly proprietary information belonging to On-Line Technologies and that the MCS100E infringed U.S. Patent No. 5,440,143. On-Line Technologies sought monetary damages, costs, expenses, injunctive relief, and other relief. On April 2, 2003, the U.S. District Court for the District of Connecticut granted our summary judgment motion and dismissed all claims brought by On-Line Technologies, Inc., though On-Line Technologies has filed an appeal with the U.S. Court of Appeals for the Federal Circuit seeking reinstatement of its claims.

Roche

We filed claims against Roche Molecular Systems, Inc., Hoffmann-La Roche, Inc., Roche Probe, Inc., F. Hoffmann-La Roche Ltd., and other potential defendants affiliated with the named defendants (Roche) in California Superior Court on October 9, 2003. Our complaint asserts, among other things, breach of contract and other contract claims against the defendants arising from agreements relating to polymerase chain reaction, or PCR, technology rights entered into between us and the defendants. Our complaint also asserts various tort claims against the defendants, including breach of trust, breach of fiduciary duty, and unfair competition, relating to our PCR rights. The defendants acts and omissions that form the basis of the complaint include, among other things, the: (i) defendants failure to abide by contractual provisions intended to allow us to effectively compete with the defendants with respect to (a) sales of diagnostic PCR products and (b) conveyance of diagnostic PCR rights to third parties; (ii) defendants failure to pay us requisite royalties for sales by them of thermal cyclers and other products; (iii) defendants failure to negotiate in good faith new agreements directed at modifying the relationship between the parties in accordance with principles set forth in an existing letter agreement that states the intended framework for the negotiations (the Letter Agreement); (iv) defendants failure to provide us with diagnostic PCR rights on a nondiscriminatory basis as required by a European Union commission decree; (v) defendants failure to comply with their

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agreement to assign ownership to us of some PCR instrument patents and patent applications, and (vi) defendants mishandling of the prosecution of patent applications that the defendants were obligated to assign to us, in a manner that damaged us and precluded us from obtaining the full potential scope of patent protection for our instrument rights.

Contemporaneously with our filing of this complaint, we also commenced arbitration proceedings with the American Arbitration Association against the defendants asserting, among other things, patent infringement claims (both direct infringement, contributory infringement and infringement by inducing third parties to infringe), breach of contract and other contract claims, and tort claims such as breach of fiduciary duty, breach of trust, and unfair competition. The arbitration is based on our allegation that the defendants (i) have infringed our exclusive rights to PCR patents in fields exclusively licensed to us pursuant to agreements with the defendants; and (ii) by their acts and omissions, have undermined the value of our exclusive PCR rights. In both the legal complaint and the arbitration, we are seeking monetary damages, costs, expenses, injunctive relief, and other relief as the court or arbitrator deems proper.

On December 15, 2003, Roche filed a motion in California Superior Court to compel arbitration of our state court complaint and to stay the litigation. Concurrently with the motion to compel arbitration, Roche also filed with the American Arbitration Association its response to our notice of arbitration in which Roche denied all of our claims against it. Roche s response included counterclaims asserting, among other things, that our exclusive patent rights under some PCR patents licensed from Roche under an existing distribution agreement were converted into nonexclusive rights by the Letter Agreement, which was entered into subsequent to the distribution agreement. Roche also alleges that (i) we breached our contractual obligation under the Letter Agreement, including our obligation to source certain enzymes exclusively from Roche; and (ii) we failed to pay Roche the full royalties required pursuant to the distribution agreement. In its counterclaim, Roche is seeking a request for declaratory judgment confirming its assertions, interest, costs, and other relief as the arbitrator deems proper.

The claims and counterclaims described above involve PCR rights used by Applied Biosystems and also rights that Applied Biosystems has contributed to Celera Diagnostics.

On March 1, 2004, the Superior Court denied Roche s motion to compel arbitration, but Roche has appealed the decision and both the arbitration and the litigation have been stayed pending the outcome of the appeal.

Enzo Biochem

Enzo Biochem, Inc., Enzo Life Sciences, Inc., and Yale University filed a patent infringement action against us in the U.S. District Court for the District of Connecticut on June 8, 2004. The complaint alleges that we are infringing six patents. Four of these patents are assigned to Yale University and licensed exclusively to Enzo Biochem, i.e., U.S. Patent No. 4,476,928, entitled Modified Nucleotides and Polynucleotides and Complexes Formed Therefrom, U.S. Patent No. 5,449,767, entitled Modified Nucleotides and Polynucleotides and Methods of Preparing Same, U.S. Patent No. 5,328,824 entitled Methods of Using Labeled Nucleotides, and U.S. Patent No. 4,711,955, entitled Modified Nucleotides and Polynucleotides and Methods of Preparing and Using Same. The other two patents are assigned to Enzo Life Sciences, i.e., U.S. Patent No. 5,082,830 entitled End Labeled Nucleotide Probe and U.S. Patent No. 4,994,373 entitled Methods and Structures Employing Compoundly Labeled Polynucleotide Probes. The allegedly infringing products include Applied Biosystems

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sequencing reagent kits, its TaqMan® genotyping and gene expression assays, and the gene expression microarrays used with its Expression Array System. Enzo Biochem, Enzo Life Sciences, and Yale University are seeking monitary damages, costs, expenses, injunctive relief, and other relief as the court deems proper.

Bio-Rad

Bio-Rad Laboratories, Inc. filed a patent infringement, trademark infringement, and unfair competition action against us in the U.S. District Court for the Northern District of California on December 26, 2002. The complaint alleges that we are infringing Bio-Rad s U.S. Pat. No. 5,089,011, entitled Electrophoretic Sieving in Gel-Free Media with Dissolved Polymers, and infringing Bio-Rad s Bio-Rad trademark. They filed a third amended complaint against us on May 30, 2003. The allegedly infringing products according to the third amended complaint are instruments using, and reagents used for, capillary electrophoresis, and products using the BioCAD name. Bio-Rad submitted its final infringement contentions under the local court rules on April 22, 2004, and the parties held a court-ordered mediation conference on July 19, 2004. Bio-Rad is seeking monetary damages, costs, expenses, injunctive relief, and other relief as the court deems proper.

Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

PART II

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

Information about our Common Stock and its Holders

Market Information

The principal U.S. market where our Applera-Applied Biosystems stock and Applera-Celera stock are traded is the New York Stock Exchange, although our stock is also traded on the Pacific Exchange.

Applera-Applied Biosystems stock is listed on the New York Stock Exchange under the trading symbol ABI and is intended to reflect the relative performance of Applied Biosystems. Applera-Celera stock is listed on the New York Stock Exchange under the trading symbol CRA and is intended to reflect the relative performance of Celera Genomics. There is no single security that represents our performance as a whole, nor is there a separate security traded for Celera Diagnostics.

Holders of Applera-Applied Biosystems stock and Applera-Celera stock are stockholders of Applera. Applied Biosystems and Celera Genomics are not separate legal entities, and holders of these stocks are stockholders of a single company, Applera. As a result, holders of these stocks are subject to all of the risks associated with an investment in Applera and all of its businesses, assets, and liabilities.

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The high and low sales prices of Applera-Applied Biosystems stock and Applera-Celera stock for each quarterly period during our 2003 and 2004 fiscal years is incorporated herein by reference to Note 12, page 71, of our 2004 Annual Report.

Holders

On September 3, 2004, the approximate number of holders of Applera-Applied Biosystems stock was 6090, and the approximate number of holders of Applera-Celera stock was 6390. The approximate number of holders is based upon the actual number of holders registered in our records at such date and does not include holders of shares in street name or persons, partnerships, associations, corporations, or other entities identified in security position listings maintained by depository trust companies. The calculation of the market value of shares held by non-affiliates shown on the cover of this report was made on the assumption that there were no affiliates other than executive officers and directors as of the date of calculation.

Dividends

Information regarding the amount of quarterly dividends during our 2003 and 2004 fiscal years is incorporated herein by reference to Note 12, page 71, of our 2004 Annual Report.

Sale of Unregistered Securities

We have not sold any securities during our 2004 fiscal year that were not registered under the Securities Act of 1933.

Issuer Purchases of Equity Securities

This table provides information regarding our purchases of shares of Applera-Applied Biosystems stock during the fourth quarter of our 2004 fiscal year.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (2)(3) (*in millions*)
April 1-30, 2004	197,499	$18.54	175,000	$97
May 1-31, 2004	3,892,298	$18.79	3,889,800	$24
June 1-30, 2004	2,437,576	$20.07	2,426,908	$
Total	6,527,373	$19.26	6,491,708	$

(1) The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced plans or programs consists of shares repurchased from employees in connection with the exercise of employee stock options, the payment of taxes relating to stock option exercises, and the payment of taxes relating to the vesting of restricted stock.

(2) We previously announced that our Board of Directors has authorized the repurchase of shares of Applera-Applied Biosystems stock from time to time to replenish shares issued under our various employee stock benefit plans. This authorization has no set dollar or time limits and delegates to our management discretion to purchase shares at times and prices it deems appropriate through open market or negotiated purchases. Accordingly, the amounts in this column do not reflect this authorization.

(3) On April 5, 2004, we announced a share repurchase authorization from our Board of Directors. Under this authorization, we were authorized to repurchase up to an additional $100 million in Applera-

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Applied Biosystems stock. We completed our repurchases under this authorization during the fourth quarter of our 2004 fiscal year.

This table provides information regarding our purchases of shares of Applera-Celera stock during the fourth quarter of our 2004 fiscal year.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (2) (*in millions*)
April 1-30, 2004	8,299	$14.21		$
May 1-31, 2004	526	$11.17		$
June 1-30, 2004	3,556	$11.41		$
Total	12,381	$13.28		$

(1) Consists of shares repurchased from employees in connection with the exercise of employee stock options, the payment of taxes relating to stock option exercises, and the payment of taxes relating to the vesting of restricted stock.

(2) We previously announced that our Board of Directors has authorized the repurchase of shares of Applera-Celera stock from time to time to replenish shares issued under our various employee stock benefit plans. This authorization has no set dollar or time limits and delegates to our management discretion to purchase shares at times and prices it deems appropriate through open market or negotiated purchases. Accordingly, the amounts in this column do not reflect this authorization. No shares were purchased under this authorization during the fourth quarter of our 2004 fiscal year.

Forward Looking Statements and Risk Factors

Some statements contained in, or incorporated by reference in, this report are forward-looking. Similarly, the press releases we issue and other public statements we make from time to time may contain language that is forward-looking. These forward-looking statements may be identified by the use of forward-looking words or phrases such as forecast, believe, expect, intend, anticipate, should, plan, estimate, and po others. The forward-looking statements contained in this report are based on our current expectations, and those made at other times will be based on our expectations when the statements are made. We cannot guarantee that any forward-looking statements will be realized.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from anticipated results or other expectations expressed in forward-looking statements. We also note that achievement of anticipated results or expectations in forward-looking statements is subject to the possibility that assumptions underlying forward-looking statements will prove to be inaccurate. Investors should bear this in mind as they consider forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include, but are not limited to, those described below under the headings Factors Relating to Applied Biosystems, Factors Relating to Celera Genomics, and Factors Relating to Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics.

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Also, we note that owners of Applera-Applied Biosystems stock and Applera-Celera stock are subject to risks arising from their ownership of common stock of a corporation with two separate classes of common stock. The risks and uncertainties that arise from our capital structure, particularly our two separate classes of common stock, include, but are not limited to, those described below under the heading Risks Relating to a Capital Structure with Two Separate Classes of Common Stock.

Factors Relating to Applied Biosystems

Rapidly changing technology in life sciences could make Applied Biosystems product line obsolete unless it continues to develop and manufacture new and improved products, and pursue new market opportunities.

A significant portion of the net revenues for Applied Biosystems each year is derived from products that did not exist in the prior year. Applied Biosystems products are based on complex technology which is subject to rapid change as new technologies are developed and introduced in the marketplace. Applied Biosystems future success depends on its ability to continually improve its current products, develop and introduce, on a timely and cost-effective basis, new products that address the evolving needs of its customers, and pursue new market opportunities that develop as a result of technological and scientific advances in life sciences. These new market opportunities may be outside the scope of the group s proven expertise or in areas which have unproven market demand. For example, Applied Biosystems has committed significant resources to researching, developing, marketing, and distributing new products and services designed to integrate laboratory experimentation with relevant scientific information, and to new Internet web sites devoted to promoting the group s products and supporting customer research and development activities. These are emerging business areas for Applied Biosystems, and there can be no assurance that there will be market acceptance of the utility and value of these products and services. The inability to gain market acceptance of new products and services could adversely affect the group s future operating results. The group s future success also depends on its ability to manufacture these improved and new products to meet customer demand in a timely and cost-effective manner, including its ability to resolve in a timely manner manufacturing issues that may arise from time to time as the group commences production of these complex products. Unanticipated difficulties or delays in replacing existing products with new products or in manufacturing improved or new products in sufficient quantities to meet customer demand could adversely affect future demand for the group s products and its future operating results.

Applied Biosystems relies on third parties for the manufacture of some of its products and also for the supply of some components of the products it manufactures on its own.

Although Applied Biosystems has contracts with most of these manufacturers and suppliers, there can be no assurance that their operations will not be disrupted. Applied Biosystems does not currently have alternative third party manufacturing or supply arrangements for some of the key products and key components manufactured or supplied by third parties. Although Applied Biosystems has its own manufacturing facilities, and believes it might be able to manufacture some of the products and components currently sourced from third parties, it also believes that it would take considerable time and resources to establish the capability to do so. Accordingly, if third party manufacturers or suppliers are unable or fail to fulfill their obligations to Applied Biosystems, Applied Biosystems might not be able to satisfy customer demand in a timely manner, and its business could be adversely affected.

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A significant portion of sales depends on customers capital spending policies that may be subject to significant and unexpected decreases.

A significant portion of Applied Biosystems instrument product sales are capital purchases by its customers. Applied Biosystems customers include pharmaceutical, environmental, research, biotechnology, and chemical companies, and the capital spending policies of these companies can have a significant effect on the demand for Applied Biosystems products. These policies are based on a wide variety of factors, including the resources available to make purchases, the spending priorities among various types of research equipment, and policies regarding capital expenditures during recessionary periods. Any decrease in capital spending or change in spending policies of these companies could significantly reduce the demand for Applied Biosystems products.

A substantial portion of Applied Biosystems sales is to customers at universities or research laboratories whose funding is dependent on both the amount and timing of funding from government sources.

As a result, the timing and amount of revenues from these sources may vary significantly due to factors that can be difficult to forecast. Although research funding has increased during the past several years, grants have, in the past, been frozen for extended periods or otherwise become unavailable to various institutions, sometimes without advance notice. Budgetary pressures may result in reduced allocations to government agencies that fund research and development activities. If government funding necessary to purchase Applied Biosystems products were to become unavailable to researchers for any extended period of time, or if overall research funding were to decrease, the business of Applied Biosystems could be adversely affected.

Applied Biosystems is currently and could in the future be subject to claims for infringement of patents and other intellectual property rights.

Applied Biosystems products are based on complex, rapidly developing technologies. These products could be developed without knowledge of previously filed patent applications that mature into patents that cover some aspect of these technologies. In addition, there are relatively few decided court cases interpreting the scope of patent claims in these technologies, and Applied Biosystems belief that its products do not infringe the technology covered by valid and enforceable patents could be successfully challenged by third parties. Also, in the course of its business, Applied Biosystems may from time to time have access to confidential or proprietary information of third parties, and these parties could bring a claim against Applied Biosystems asserting that Applied Biosystems had misappropriated their technologies, which though not patented are protected as trade secrets, and had improperly incorporated such technologies into Applied Biosystems products. Applied Biosystems has been made a party to litigation regarding intellectual property matters, including the litigation described in the following paragraph and elsewhere in this report, some of which, if determined adversely, could have a material adverse effect on Applied Biosystems. Due to the fact that Applied Biosystems business depends in large part on rapidly developing and dynamic technologies, there remains a constant risk of intellectual property litigation affecting the group. Applied Biosystems has from time to time been notified that it may be infringing patents and other intellectual property rights of others. It may be necessary or desirable in the future to obtain licenses relating to one or more products or relating to current or future technologies, and Applied Biosystems cannot be assured that it will be able to obtain these licenses or other rights on commercially reasonable terms.

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Several legal actions have been filed against us that could affect the intellectual property rights of Applied Biosystems and its products and services, including the following:

In response to claims by us against MJ Research, Inc., MJ Research filed counterclaims against us including, among others, allegations that we have licensed and enforced some polymerase chain reaction, or PCR, patents through anticompetitive conduct in violation of federal and state antitrust laws. Subsequently, MJ Research filed a lawsuit against us based on the allegation that four patents underlying Applied Biosystems DNA sequencing instruments were invalidly obtained because an alleged inventor, whose work was funded in part by the U.S. government, was knowingly omitted from the patent applications. MJ Research claims to be suing in the name of the U.S. government although the government has to date declined to participate in the lawsuit. The case was dismissed but the decision has been appealed by MJ Research.

Promega Corporation has filed a lawsuit against us alleging that Applied Biosystems, along with some other named defendants, is infringing two Promega patents due to the sale of forensic identification and paternity testing kits.

Beckman Coulter, Inc. has filed a lawsuit against us alleging that Applied Biosystems is infringing three Beckman Coulter patents. The allegedly infringing products are Applied Biosystems capillary electrophoresis sequencing and genetic analysis instruments, and PCR and real-time PCR systems.

Genetic Technologies Limited has filed a lawsuit against us alleging that we are infringing two of its patents due to the sale of cystic fibrosis reagent kits, some of our TaqMan® genotyping and gene expression products and services, and the Celera Discovery System . Genetic Technologies has also alleged that haplotyping analysis performed by our businesses infringes these patents.

In response to an arbitration claim filed by us against Roche Molecular Systems, Inc., Hoffmann-LaRoche, Inc., Roche Probe, Inc., F. Hoffmann-LaRoche Ltd., and other potential defendants affiliated with those defendants, they have asserted counterclaims against us in the arbitration that could affect our exclusive rights to some PCR patents licensed from them.

Enzo Biochem, Inc., Enzo Life Sciences, Inc., and Yale University have filed a lawsuit against us alleging that we are infringing six patents due to the sale of sequencing reagent kits, TaqMan® genotyping and gene expression assays, and the gene expression microarrays used with the Applied Biosystems Expression Array System.

Bio-Rad Laboratories, Inc. has filed a lawsuit against us alleging that we are infringing one of its patents due to our sale of instruments using, and reagents used for, capillary electrophoresis, and one of its trademarks due to our use of the BioCAD name.

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These cases are described in further detail above in Item 3 of this report under the heading Legal Proceedings. The cost of litigation and the amount of management time associated with these cases is expected to be significant. There can be no assurance that these matters will be resolved favorably; that we will not be enjoined from selling the products or services in question or other products or services as a result; or that any monetary or other damages assessed against us will not have a material adverse effect on the financial condition of our company, Applied Biosystems, Celera Genomics, or Celera Diagnostics.

Since Applied Biosystems business is dependent on foreign sales, fluctuating currencies will make revenues and operating results more volatile.

Approximately 50% of Applied Biosystems net revenues for our 2004 fiscal year were derived from sales to customers outside of the U.S. The majority of these sales were based on the relevant customer s local currency. A significant portion of the related costs for Applied Biosystems are based on the U.S. dollar. As a result, Applied Biosystems reported and anticipated operating results and cash flows are subject to fluctuations due to material changes in foreign currency exchange rates that are beyond Applied Biosystems control.

Integrating acquired technologies may be costly and may not result in technological advances.

The future growth of Applied Biosystems depends in part on its ability to acquire complementary technologies through acquisitions and investments. The consolidation of employees, operations, and marketing and distribution methods could present significant managerial challenges. For example, Applied Biosystems may encounter operational difficulties in the integration of manufacturing or other facilities. In addition, technological advances resulting from the integration of technologies may not be achieved as successfully or rapidly as anticipated, if at all.

Applied Biosystems businesses, particularly those focused on developing and marketing information-based products and services, depend on the continuous, effective, reliable, and secure operation of its computer hardware, software, and Internet applications and related tools and functions.

Applied Biosystems business requires manipulating and analyzing large amounts of data, and communicating the results of the analysis to its internal research personnel and to its customers via the Internet. Also, Applied Biosystems relies on a global enterprise software system to operate and manage its business. Applied Biosystems business therefore depends on the continuous, effective, reliable, and secure operation of its computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that Applied Biosystems hardware or software malfunctions or access to Applied Biosystems data by internal research personnel or customers through the Internet is interrupted, Applied Biosystems business could suffer. Also, a recent upgrade of our global enterprise software system was performed and we do not believe we will be able to adequately assess the success of the upgrade and the operation of the software until we complete our first quarterly financial close following the upgrade, which close will occur during September 2004. If we encounter difficulties with the upgrade or if we determine that the upgraded software does not operate effectively, these circumstances could interfere with our business operations.

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Applied Biosystems computer and communications hardware is protected through physical and software safeguards. However, it is still vulnerable to fire, storm, flood, power loss, earthquakes, telecommunications failures, physical or software break-ins, software viruses, and similar events. In addition, Applied Biosystems online products and services are complex and sophisticated, and as such, could contain data, design, or software errors that could be difficult to detect and correct. Software defects could be found in current or future products. If Applied Biosystems fails to maintain and further develop the necessary computer capacity and data to support its computational needs and its customers access to information-based product and service offerings, it could experience a loss of or delay in revenues or market acceptance. In addition, any sustained disruption in Internet access provided by third parties could adversely affect Applied Biosystems.

Earthquakes could disrupt operations in California.

The headquarters and principal operations of Applied Biosystems are located in the San Francisco Bay area, a region near major California earthquake faults. The ultimate impact of earthquakes on Applied Biosystems, its significant suppliers, and the general infrastructure is unknown, but operating results could be materially affected in the event of a major earthquake.

Applera-Applied Biosystems stock price is volatile.

The market price of Applera-Applied Biosystems stock has been and may continue to be volatile due to the risks and uncertainties described in this section of this report, as well as other factors that may have affected or may in the future affect the market price, such as:

- conditions and publicity regarding the genomics, biotechnology, pharmaceutical, or life sciences industries generally;
- price and volume fluctuations in the stock market at large which do not relate to Applied Biosystems operating performance; and
- comments by securities analysts or government officials, including with regard to the viability or profitability of the biotechnology sector generally or with regard to intellectual property rights of life science companies, or Applied Biosystems ability to meet market expectations.

The stock market has from time to time experienced extreme price and volume fluctuations that are unrelated to the operating performance of particular companies. In the past, companies that have experienced volatility have sometimes been the subjects of securities class action litigation. If litigation was instituted on this basis, it could result in substantial costs and a diversion of management s attention and resources.

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Factors Relating to Celera Genomics

Celera Genomics has incurred net losses to date and may not achieve profitability.

Celera Genomics has accumulated net losses of approximately $717 million as of June 30, 2004, and expects that it will continue to incur net losses for the foreseeable future. These cumulative losses are expected to increase as Celera Genomics continues to make investments in new technology and product development, including its investments in the discovery and development of therapeutic products, as well as investments in diagnostics through Celera Diagnostics, its joint venture with Applied Biosystems. Celera Genomics will record all initial cash operating losses of Celera Diagnostics up to a maximum of $300 million, after which any additional operating losses would be shared equally by Celera Genomics and Applied Biosystems. However, Applied Biosystems reimburses Celera Genomics for all tax benefits generated by Celera Diagnostics to the extent such tax benefits are used by Applied Biosystems, and the effect of recording Celera Diagnostics operating losses on Celera Genomics net losses will be partially offset by this reimbursement. Celera Diagnostics has accumulated cash operating losses of approximately $125 million as of June 30, 2004. As an early stage business, Celera Genomics faces significant challenges in expanding its business operations into the discovery and development of therapeutic products. As a result, there is a high degree of uncertainty that Celera Genomics will be able to achieve profitable operations.

The marketing and distribution agreement with Applied Biosystems may not generate significant royalty payments.

Applied Biosystems became the exclusive distributor of the Celera Discovery System and Celera Genomics related human genomic and other biological and medical information under the terms of a ten-year marketing and distribution agreement that was effective in April 2002. Under the terms of that agreement, Applied Biosystems is obligated to pay a royalty to Celera Genomics based on sales of some products sold by Applied Biosystems on and after July 1, 2002. This royalty rate and the corresponding payments to be made to Celera Genomics were based on the sales of these products that the groups anticipated at the time of the execution of the agreement. Applied Biosystems has not guaranteed any minimum royalty payments to Celera Genomics, and the actual amount of royalty payments to be paid to Celera Genomics depends on Applied Biosystems ability to successfully commercialize the products subject to the royalty. Applied Biosystems has not proven its ability to successfully commercialize these products. Celera Genomics believes that in order for Applied Biosystems sales of these products to meet original expectations, Applied Biosystems will have to continue devoting a significant amount of its resources to researching, developing, marketing, and distributing them. However, Celera Genomics has no control over the amount and timing of Applied Biosystems use of its resources, including for products subject to the royalty. In addition, the market for these products is intensely competitive, and there can be no assurance that there will be market acceptance of the utility and value of these product offerings.

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Celera Genomics has not sought any new customers for its Celera Discovery System and related information products and services since June 30, 2002, and therefore its future revenues from its sale of these products and services will be limited.

Under the terms of the marketing and distribution agreement between Celera Genomics and Applied Biosystems described in the preceding paragraph, Celera Genomics receives all revenues under, and is responsible for all costs and expenses associated with, Celera Discovery System and related information contracts that were entered into on or prior to June 30, 2002. However, the Applied Biosystems took full responsibility for marketing and contracting for the Celera Discovery System and related products and services after that date. Accordingly, Celera Genomics does not expect any revenues from the Celera Discovery System and related products and services other than under contracts existing on June 30, 2002, so long as they remain in effect, and from potential royalty payments from Applied Biosystems under the marketing and distribution agreement. Applied Biosystems has agreed to reimburse Celera Genomics for any shortfall in earnings before interest, taxes, depreciation, and amortization from these contracts below a total of $62.5 million during the four fiscal years ending with the 2006 fiscal year, if the shortfall is due to the actions of Applied Biosystems including changes in marketing strategy for the Celera Discovery System. However, this commitment is also subject to Celera Genomics otherwise continuing to perform under these contracts, and does not protect Celera Genomics from lost revenue due to other circumstances such as a customer bankruptcy or default. Although under some contracts with existing Celera Discovery System customers Celera Genomics is entitled to milestone payments or future royalties based on products developed by its customers, Celera Genomics believes these arrangements are unlikely to produce any significant revenue for the group.

Because of the close working relationship between Celera Genomics and Applied Biosystems under the marketing and distribution agreement, it may be difficult to ascertain responsibility for claims, liabilities, or other issues that may arise under Celera Discovery System contracts or the marketing and distribution agreement.

Under the marketing and distribution agreement described above, the two groups have agreed to cooperation guidelines to enable Celera Genomics to perform its obligations under existing Celera Discovery System agreements and to facilitate the development of Applied Biosystems products covered by the agreement. These guidelines provide for the application of relevant resources and expertise of the groups to the relationship, and have led to a close working relationship among personnel within the two groups. Because of this working relationship, if any customers assert any claims under Celera Discovery System contracts, it may be difficult to determine which group was responsible for the actions that gave rise to the claim. In addition, Applied Biosystems may from time to time take good faith actions in pursuit of its marketing strategy that affect Celera Discovery System contracts that were in existence on June 30, 2002. Because of the working relationship between the two groups, it may be difficult to determine whether the actions of Applied Biosystems are within the scope of the reimbursement obligation described above.

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Celera Genomics ability to develop and commercialize proprietary therapeutic products is unproven.

As Celera Genomics expands its business operations in the area of therapeutic product discovery and development, it faces the difficulties inherent in developing and commercializing these products. It is possible that Celera Genomics discovery and development efforts will not result in any commercial products. In particular, Celera Genomics and its collaborators are seeking to develop new therapeutic products based on information derived from the study of the genetic material of organisms, or genomics, and the study of proteins, or proteomics. Also pursuant to its current business and scientific plan, Celera Genomics is seeking to capitalize on its relationship with Celera Diagnostics through the evaluation of the therapeutic relevance of targets that Celera Diagnostics may identify in the disease association studies it is performing on its own behalf as well as additional disease association studies it has agreed to perform specifically for Celera Genomics. To our knowledge, no one to date has developed or commercialized any therapeutic products based on the Celera Genomics genomics or proteomics technologies or Celera Diagnostics disease association studies, and therefore the benefit of these technologies and studies to the development of therapeutics is unproven. In addition, while Celera Diagnostics has agreed to perform some studies specifically for Celera Genomics, Celera Diagnostics is not obligated to continue the disease association studies that it performs on its own behalf. If Celera Diagnostics discontinues in whole or in part its disease association study program, or if this program or the studies performed specifically for Celera Genomics do not result in any targets with therapeutic relevance, Celera Genomics business and scientific plan could be adversely affected.

Therapeutic product candidates may never result in a commercialized product.

All of Celera Genomics therapeutic product candidates are in various stages of research and development and will require significant additional research and development efforts by Celera Genomics or its collaborators before they can be marketed. These efforts include extensive preclinical and clinical testing and lengthy regulatory review and clearance or approval by the U.S. Food and Drug Administration, or FDA, and comparable agencies in other countries. Celera Genomics development of therapeutic products is highly uncertain and subject to a number of significant risks. To date, Celera Genomics has not commercialized a therapeutic product and Celera Genomics does not expect any of its therapeutic product candidates to be commercially available for a number of years, if ever. Therapeutic product candidates that appear to be promising at early stages of development may not be developed into commercial products, or may not be successfully marketed, for a number of reasons, including:

Celera Genomics or its collaborators may not successfully complete any research and development efforts;

Celera Genomics or its collaborators may not successfully build the necessary preclinical and clinical development organizations;

any therapeutic product candidates that Celera Genomics or its collaborators develop may be found during preclinical testing or clinical trials to be ineffective or to cause harmful side effects;

Celera Genomics or its collaborators may fail to obtain required regulatory approvals for products they develop;

Celera Genomics or its collaborators may be unable to manufacture enough of any potential products at an acceptable cost and with appropriate quality;

Celera Genomics or its collaborators may fail to build necessary distribution channels;

Celera Genomics or its collaborators products may not be competitive with other existing or future products;

adequate reimbursement for Celera Genomics or its collaborators products may not be available to healthcare providers and patients from the government or insurance companies; and

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Celera Genomics or its collaborators may be unable to obtain necessary intellectual property protection, or third parties may own proprietary rights that prevent Celera Genomics or its collaborators from commercializing their products.

If Celera Genomics fails to maintain its existing collaborative relationships and enter into new collaborative relationships, or if collaborators do not perform under collaboration agreements, development of its therapeutic product candidates could be delayed.

Celera Genomics strategy for the discovery, development, clinical testing, manufacturing and commercialization of most of its therapeutic product candidates includes entering into collaborations with partners. Although Celera Genomics has expended, and continues to expend, time and money on internal research and development programs, it may be unsuccessful in creating therapeutic product candidates that would enable it to form additional collaborations and receive milestone and/or royalty payments from collaborators.

Each of Celera Genomics existing collaboration agreements may be canceled under some circumstances. In addition, the amount and timing of resources to be devoted to research, development, clinical trials and commercialization activities by Celera Genomics collaborators in some cases are not within Celera Genomics control. Celera Genomics cannot ensure that its collaborators will perform their obligations as expected. If any of Celera Genomics collaborators terminate their agreements or otherwise fail to conduct their collaborative activities in a timely manner, the development or commercialization of therapeutic products may be delayed or otherwise adversely affected. If in some cases Celera Genomics assumes responsibilities for continuing programs on its own after termination of a collaboration, Celera Genomics may be required to devote additional resources to product development and commercialization or Celera Genomics may need to cancel some development programs.

If Celera Genomics or its collaborators fail to satisfy regulatory requirements for any therapeutic product candidate, Celera Genomics or its collaborators will be unable to complete the development and commercialization of that product.

Celera Genomics is currently developing its internal capability to move potential products through clinical testing, manufacturing and the approval processes of the FDA and comparable agencies in other countries. In the U.S., either Celera Genomics or its collaborators must show through pre-clinical studies and clinical trials that each of Celera Genomics or its collaborators therapeutic product candidates is safe and effective in humans for each indication before obtaining regulatory clearance from the FDA for the commercial sale of that product. Outside of the U.S., the regulatory requirements vary from country to country. If Celera Genomics or its collaborators fail to adequately show the safety and effectiveness of a therapeutic product, regulatory clearance or approval could be delayed or denied. The results from pre-clinical studies may be different from the results that are obtained in clinical trials. Celera Genomics cannot be certain that it or its collaborators will show sufficient safety and effectiveness in their clinical trials to allow them to obtain the needed regulatory clearance or approval for any therapeutic product candidate. The regulatory review and approval process can take many years and require substantial expense and may not be successful. Many companies in the therapeutic industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier studies.

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Even if Celera Genomics or its collaborators obtain regulatory clearance or approval for a particular therapeutic product, that product will be subject to risks and uncertainties relating to regulatory compliance, including post-approval clinical studies and inability to meet the compliance requirements of the FDA s Good Manufacturing Practices regulations. In addition, identification of some adverse side effects after a therapeutic product is on the market or the occurrence of manufacturing problems could cause subsequent suspension of product manufacture or withdrawal of approval, or could require reformulation of a therapeutic product, additional testing, or changes in labeling of the product. This could delay or prevent Celera Genomics from generating revenues from the sale of that therapeutic product.

For some of Celera Genomics research and product development programs, particularly its proteomics efforts, Celera Genomics needs access to human and other tissue samples from diseased and healthy individuals, other biological materials, and related clinical and other information, which may be in limited supply.

Celera Genomics may not be able to obtain or maintain access to these materials and information on acceptable terms, or may not be able to obtain needed consents from individuals providing tissue or other samples. In addition, government regulation in the U.S. and foreign countries could result in restricted access to, or use of, human and other tissue samples. If Celera Genomics loses access to sufficient numbers or sources of tissue samples or other required biological materials, or if tighter restrictions are imposed on the use of related clinical or other information or information generated from tissue samples or other biological materials, these research and development programs and Celera Genomics business could be adversely affected.

The pharmaceutical industry is intensely competitive and evolving.

There is intense competition among pharmaceutical and biotechnology companies attempting to discover candidates for potential new therapeutic products. These companies may:

develop new therapeutic products in advance of Celera Genomics or its collaborators;

develop therapeutic products which are more effective as therapeutics, or more cost-effective than those developed by Celera Genomics or its collaborators;

obtain regulatory approvals of their therapeutic products more rapidly than Celera Genomics or its collaborators; or

obtain patent protection or other intellectual property rights that would limit the ability of Celera Genomics or its collaborators to develop and commercialize therapeutic products.

Introduction of new products may expose Celera Genomics to product liability claims.

New products developed by Celera Genomics or its collaborators could expose Celera Genomics to potential product liability risks that are inherent in the testing, manufacturing, marketing and sale of human therapeutic products. Product liability claims or product recalls, regardless of the ultimate outcome, could require Celera Genomics to spend significant time and money in litigation and to pay significant damages. Although Celera Genomics expects to seek and maintain product liability insurance to cover claims relating to the testing and use of therapeutic products, there can be no assurance that such insurance will be available on commercially reasonable terms, if at all, or that the amount of coverage obtained will be adequate to cover losses from any particular claim.

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Therapeutics discovery and development is a highly technical field and there is a competitive market for personnel with the expertise needed for the expansion of Celera Genomics business operations within this field.

Celera Genomics believes that in order to develop and commercialize therapeutic products, it will need to recruit and retain scientific and management personnel having specialized training or advanced degrees, or otherwise having the technical background, necessary for an understanding of therapeutic products. There is a shortage of qualified scientific and management personnel who possess this technical background. Celera Genomics competes for these personnel with other pharmaceutical and biotechnology companies, academic institutions and government entities. If Celera Genomics is unable to retain and attract qualified scientific and management personnel, the growth of the group s business operations in the area of therapeutic product discovery and development could be delayed or curtailed.

Celera Genomics could incur liabilities relating to hazardous materials that it uses in its research and development activities.

Celera Genomics research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive materials. In the event of an accidental contamination or injury from these materials, Celera Genomics could be held liable for damages in excess of its resources.

Celera Genomics business depends on the continuous, effective, reliable, and secure operation of its computer hardware, software, and Internet applications and related tools and functions.

Celera Genomics business requires manipulating and analyzing large amounts of data, and communicating the results of the analysis to its internal research personnel and to its customers via the Internet. Also, Celera Genomics relies on a global enterprise software system to operate and manage its business. Celera Genomics business therefore depends on the continuous, effective, reliable, and secure operation of its computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that Celera Genomics hardware or software malfunctions or access to Celera Genomics data by Celera Genomics internal research personnel or customers through the Internet is interrupted, the group s business could suffer. Also, a recent upgrade of our global enterprise software system was performed and we do not believe we will be able to adequately assess the success of the upgrade and the operation of the software until we complete our first quarterly financial close following the upgrade, which close will occur during September 2004. If we encounter difficulties with the upgrade or if we determine that the upgraded software does not operate effectively, these circumstances could interfere with our business operations.

Celera Genomics computer and communications hardware is protected through physical and software safeguards. However, it is still vulnerable to fire, storm, flood, power loss, earthquakes, telecommunications failures, physical or software break-ins, software viruses, and similar events. In addition, Celera Genomics online products are complex and sophisticated, and as such, could contain data, design, or software errors that could be difficult to detect and correct. Software defects could be found in current or future products. If Celera Genomics fails to maintain and further develop the necessary computer capacity and data to support its therapeutic products discovery and development programs and its online products, it could experience a loss of or delay in revenues. In addition, any sustained disruption in Internet access provided by third parties could adversely affect Celera Genomics business.

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Celera Genomics competitive position depends on maintaining its intellectual property protection and obtaining licenses to intellectual property it may need from others.

Celera Genomics ability to compete and to achieve and maintain profitability depends on its ability to protect its proprietary discoveries and technologies, in large part, through obtaining and enforcing patent rights, obtaining copyright protection, maintaining its trade secrets, and operating without infringing the intellectual property rights of others. Celera Genomics ability to obtain patent protection for the inventions it makes is uncertain. The patentability of biotechnology and pharmaceutical inventions involves complex factual and legal questions. As a result, it is difficult to predict whether patents will issue or the breadth of claims that will be allowed in biotechnology and pharmaceutical patents. This may be particularly true with regard to the patenting of gene sequences, gene functions, and genetic variations. In this regard, the U.S. Patent and Trademark Office has adopted guidelines for use in the review of the utility of inventions, particularly biotechnology inventions. These guidelines increased the amount of evidence required to demonstrate utility in order to obtain a patent in the biotechnology field, making patent protection more difficult to obtain. Although others have been successful in obtaining patents to biotechnology inventions, since the adoption of these guidelines, these patents have been issued with increasingly less frequency. As a result, patents may not issue from patent applications that Celera Genomics may own or license if the applicant is unable to satisfy the new guidelines.

The U.S. Patent and Trademark Office has issued several patents to third parties covering inventions involving single nucleotide polymorphisms or SNPs, naturally occurring genetic variations that scientists believe can be correlated with susceptibility to disease, disease prognosis, therapeutic efficiency, and therapeutic toxicity. These inventions are subject to the same new guidelines as other biotechnology inventions. In addition, Celera Genomics may need to obtain rights to patented SNPs in order to develop, use and sell analyses of the overall human genome or particular full-length genes. These licenses may not be available to Celera Genomics on commercially acceptable terms, or at all.

In some instances, patent applications in the U.S. are maintained in secrecy until a patent issues. In most instances, the content of U.S. and international patent applications is made available to the public approximately 18 months after the initial filing from which priority is claimed. As a result, Celera Genomics cannot be certain that others have not filed patent applications for inventions covered by Celera Genomics patent applications or that Celera Genomics inventors were the first to make the invention. Accordingly, Celera Genomics patent applications may be preempted or Celera Genomics may have to participate in interference proceedings before the U.S. Patent and Trademark Office. These proceedings determine the priority of invention and the right to a patent for the claimed invention in the U.S.

Furthermore, lawsuits may be necessary to enforce any patents issued to Celera Genomics or to determine the scope and validity of the rights of third parties. Lawsuits and interference proceedings, even if they are successful, are expensive to pursue, and Celera Genomics could use a substantial amount of its financial resources in either case. An adverse outcome could subject Celera Genomics to significant liabilities to third parties and require Celera Genomics to license disputed rights from third parties or to cease using the technology.

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Celera Genomics may be dependent on protecting its proprietary databases through copyright law to prevent other organizations from taking information from those databases and copying and reselling it. Copyright law currently provides uncertain protection regarding the copying and resale of factual data. Changes in copyright law could either expand or reduce the extent to which Celera Genomics and its customers are able to protect their intellectual property. Accordingly, Celera Genomics is uncertain as to whether it can prevent such copying or resale through copyright law.

Celera Genomics also relies on trade secret protection for its confidential and proprietary information and procedures, including procedures related to sequencing genes and to searching and identifying important regions of genetic information. Celera Genomics protects its trade secrets through recognized practices, including access control, confidentiality and nonuse agreements with employees, consultants, collaborators and customers, and other security measures. These confidentiality and nonuse agreements may be breached, however, and Celera Genomics may not have adequate remedies for a breach. In addition, Celera Genomics trade secrets may otherwise become known or be independently developed by competitors. Accordingly, it is uncertain whether Celera Genomics reliance on trade secret protection will be adequate to safeguard its confidential and proprietary information and procedures.

Disputes may arise in the future with regard to the ownership of rights to any invention developed with collaborators. These and other possible disagreements with collaborators could lead to delays in the achievement of milestones or receipt of royalty payments or in research, development and commercialization of Celera Genomics products. In addition, these disputes could require or result in lawsuits or arbitration. Lawsuits and arbitration are time-consuming and expensive. Even if Celera Genomics wins, the cost of these proceedings could adversely affect its business, financial condition and operating results.

Celera Genomics may infringe the intellectual property rights of third parties and may become involved in expensive intellectual property litigation.

The intellectual property rights of biotechnology companies, including Celera Genomics, are generally uncertain and involve complex legal, scientific and factual questions. Celera Genomics success in therapeutic product discovery and development may depend, in part, on its ability to operate without infringing the intellectual property rights of others and to prevent others from infringing its intellectual property rights.

There has been substantial litigation regarding patents and other intellectual property rights in the biotechnology, and pharmaceutical, and diagnostic industries. Celera Genomics may become a party to patent litigation or proceedings at the U.S. Patent and Trademark Office to determine its patent rights with respect to third parties. Interference proceedings may be necessary to establish which party was the first to make the invention sought to be patented. Celera Genomics may become involved in patent litigation against third parties to enforce its patent rights, to invalidate patents held by the third parties, or to defend against these claims. The cost to Celera Genomics of any patent litigation or similar proceeding could be substantial, and it may absorb significant management time. If infringement litigation against Celera Genomics is resolved unfavorably to Celera Genomics, Celera Genomics may be enjoined from manufacturing or selling its products or services without a license from a third party. Celera Genomics may not be able to obtain a license on commercially acceptable terms, or at all.

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Ethical, legal, and social issues related to the use of genetic information and genetic testing may cause less demand for Celera Genomics products.

Genetic testing has raised issues regarding confidentiality and the appropriate uses of the resulting information. For example, concerns have been expressed regarding the use of genetic test results by insurance carriers or employers to discriminate on the basis of this information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities calling for limits on or regulation of the use of genetic testing or prohibiting testing for genetic predisposition to some diseases, particularly those that have no known cure. Any of these scenarios could reduce the potential markets for products of Celera Genomics.

Future acquisitions and other transactions may absorb significant resources, may be unsuccessful and could dilute the holders of Applera-Celera stock.

Celera Genomics expects to pursue acquisitions, investments, and other strategic relationships and alliances. Acquisitions, investments and other strategic relationships and alliances may involve significant cash expenditures, debt incurrence, additional operating losses, and expenses that could have a material effect on Celera Genomics financial condition and operating results. Acquisitions involve numerous other risks, including:

difficulties integrating acquired technologies and personnel into the business of Celera Genomics;

diversion of management from daily operations;

inability to obtain required financing on favorable terms;

entry into new markets in which Celera Genomics has little previous experience;

potential loss of key employees, key contractual relationships, or key customers of acquired companies or of Celera Genomics; and

assumption of the liabilities and exposure to unforeseen liabilities of acquired companies.

It may be difficult for Celera Genomics to complete these transactions quickly and to integrate these acquired operations efficiently into its current business operations. Any acquisitions, investments or other strategic relationships and alliances by Celera Genomics may ultimately have a negative impact on its business and financial condition. For example, future acquisitions may not be as successful as originally anticipated and may result in special charges. We have incurred special charges in recent years as a result of acquisitions. As a result of Celera Genomics acquisition of Paracel, Inc., we incurred charges for impairment of goodwill, intangibles and other assets and other charges in the amounts of $69.1 million during our 2001 fiscal year and $25.9 million during our 2002 fiscal year. Similarly, as a result of Applied Biosystems acquisition of Boston Probes, Inc., we incurred charges for the impairment of patents and acquired technology in the amount of $14.9 million during our 2004 fiscal year.

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In addition, acquisitions and other transactions may involve the issuance of a substantial amount of Applera-Celera stock without the approval of the holders of Applera-Celera stock. Any issuances of this nature will be dilutive to holders of Applera-Celera stock.

Earthquakes could disrupt operations in California.

Celera Genomics has research and development and administrative facilities in South San Francisco, California. South San Francisco is located near major California earthquake faults. The ultimate impact of earthquakes on Celera Genomics, its significant suppliers, and the general infrastructure is unknown, but operating results could be materially affected in the event of a major earthquake.

Applera-Celera stock price is volatile.

The market price of Applera-Celera stock has been and may continue to be volatile due to the risks and uncertainties described in this section of this report, as well as other factors that may have affected or may in the future affect the market price, such as:

- conditions and publicity regarding the genomics, biotechnology, pharmaceutical, or life sciences industries generally;
- price and volume fluctuations in the stock market at large which do not relate to Celera Genomics operating performance; and
- comments by securities analysts or government officials, including with regard to the viability or profitability of the biotechnology sector generally or with regard to intellectual property rights of life science companies, or Celera Genomics ability to meet market expectations.

The stock market has from time to time experienced extreme price and volume fluctuations that are unrelated to the operating performance of particular companies. In the past, companies that have experienced volatility have sometimes been the subjects of securities class action litigation. If litigation was instituted on this basis, it could result in substantial costs and a diversion of management s attention and resources.

Our company is subject to a purported class action lawsuit relating to its 2000 offering of shares of Applera-Celera stock that may be expensive and time consuming.

Our company and some of our officers are defendants in a lawsuit purportedly brought on behalf of purchasers of Applera-Celera stock in our follow-on public offering of Applera-Celera stock completed on March 6, 2000. In the offering, we sold an aggregate of approximately 4.4 million shares of Applera-Celera stock at a public offering price of $225 per share. The lawsuit was commenced with the filing of several complaints in 2000, which have been consolidated into a single case. The consolidated complaint generally alleges that the prospectus used in connection with the offering was inaccurate or misleading because it failed to adequately disclose the alleged opposition of the Human Genome Project and two of its supporters, the governments of the U.S. and the U.K., to providing patent protection to our genomic-based products. Although Celera Genomics has never sought, or intended to seek, a patent on the basic human genome sequence data, the complaint also alleges that we did not adequately disclose the risk that Celera Genomics would not be able to patent this data. The consolidated complaint seeks unspecified monetary damages, rescission, costs and expenses, and other relief as the court deems proper. Although we believe the asserted claims are without merit and intend to defend the case vigorously, the outcome of this or any other litigation is inherently uncertain. The defense of this case will require management attention and resources.

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Factors Relating to Celera Diagnostics, a 50/50 Joint Venture between Applied Biosystems and Celera Genomics

Celera Diagnostics ability to develop and commercialize proprietary diagnostic products is unproven. Celera Diagnostics faces the difficulties inherent in developing and commercializing diagnostic products. It is possible that Celera Diagnostics discovery and development efforts will not result in any new commercial products or services. In particular, Celera Diagnostics and its collaborators are seeking to develop new diagnostic products based on information derived from the study of the genetic material of organisms, or genomics. This method carries inherent risks, as only a limited number of diagnostic products based on genomic discoveries have been developed and commercialized to date.

Diagnostic product candidates may never result in a commercialized product. Most of Celera Diagnostics potential diagnostic products are in various stages of research and development and will require significant additional research and development efforts by Celera Diagnostics or its collaborators before they can be marketed. These efforts include extensive clinical testing and may require lengthy regulatory review and clearance or approval by the U.S. Food and Drug Administration, or FDA, and comparable agencies in other countries. Celera Diagnostics development of new diagnostic products is highly uncertain and subject to a number of significant risks. Diagnostic product candidates that appear to be promising at early stages of development may not be developed into commercial products, or may not be successfully marketed, for a number of reasons, including:

Celera Diagnostics or its collaborators may not successfully complete any research and development efforts;

any diagnostic products that Celera Diagnostics or its collaborators develop may be found during clinical trials to have limited medical value;

Celera Diagnostics or its collaborators may fail to obtain required regulatory clearances or approvals for products they develop;

Celera Diagnostics or its collaborators may be unable to manufacture enough of any potential products at an acceptable cost and with appropriate quality;

any diagnostic products Celera Diagnostics or its collaborators develop may not be competitive with other existing or future products;

adequate reimbursement for Celera Diagnostics and its collaborators products may not be available to physicians or patients from the government or insurance companies; and

Celera Diagnostics may be unable to obtain necessary intellectual property protection, or third parties may own proprietary rights that prevent Celera Diagnostics or its collaborators from commercializing their products.

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If Celera Diagnostics or its collaborators fail to satisfy regulatory requirements for any diagnostic product candidate, they may be unable to complete the development and commercialization of that product.

Celera Diagnostics is currently developing its capability to move potential products through clinical testing, manufacturing, and the approval processes of the FDA and comparable agencies in other countries. In the U.S., either Celera Diagnostics or its collaborators must show through pre-clinical studies and clinical trials that each of Celera Diagnostics or its collaborators diagnostic product candidates is safe and effective for each indication before obtaining regulatory clearance or approval from the FDA for the commercial sale of that product as an *in-vitro* diagnostic product with clinical claims. Outside of the U.S., the regulatory requirements vary from country to country. If Celera Diagnostics or its collaborators fail to adequately show the safety and effectiveness of a diagnostic product, regulatory clearance or approval could be delayed or denied. The results from pre-clinical studies may be different from the results that are obtained in clinical trials. Celera Diagnostics cannot be certain that it or its collaborators will show sufficient safety and effectiveness in its clinical trials to allow them to obtain the needed regulatory clearance or approval. The regulatory review and approval process can take many years and require substantial expense and may not be successful. A number of companies in the diagnostics industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier studies.

Even if Celera Diagnostics or its collaborators obtain regulatory clearance or approval for a product, that product will be subject to risks and uncertainties relating to regulatory compliance, including post-clearance or approval clinical studies and inability to meet the compliance requirements of the FDA s Quality System Regulations. In addition, the occurrence of manufacturing problems could cause subsequent suspension of product manufacture or withdrawal of clearance or approval, or could require reformulation of a diagnostic product, additional testing, or changes in labeling of the product. This could delay or prevent Celera Diagnostics from generating revenues from the sale of that diagnostic product.

Celera Diagnostics products may not be fully accepted by physicians and laboratories.

Celera Diagnostics growth and success will depend on market acceptance by physicians and laboratories of its products as clinically useful and cost-effective. Celera Diagnostics expects that most of its products will use genotyping and gene expression information to predict predisposition to diseases, disease progression or severity, or responsiveness to treatment. Market acceptance will depend on the widespread acceptance and use by doctors and clinicians of genetic testing for these purposes. The use of genotyping and gene expression information by doctors and clinicians for these purposes is relatively new. Celera Diagnostics cannot be certain that doctors and clinicians will want to use its products designed for these purposes.

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Even if genetic testing is accepted as a method to manage health care, Celera Diagnostics cannot be certain that its products will be accepted in the clinical diagnostic market. If genetic testing becomes widely accepted in the clinical diagnostic market, Celera Diagnostics cannot predict the extent to which doctors and clinicians may be willing to utilize Celera Diagnostics products in providing patient care. Doctors and clinicians may prefer competing technologies and products that can be used for the same purposes as Celera Diagnostics products.

Ethical, legal, and social issues related to the use of genetic information and genetic testing may cause less demand for Celera Diagnostics products.

Genetic testing has raised issues regarding confidentiality and the appropriate uses of the resulting information. For example, concerns have been expressed regarding the use of genetic test results by insurance carriers or employers to discriminate on the basis of this information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities calling for limits on or regulation of the use of genetic testing or prohibiting testing for genetic predisposition to some diseases, particularly those that have no known cure. Any of these scenarios could reduce the potential markets for products of Celera Diagnostics.

If insurance companies and other third-party payors do not reimburse doctors and patients for Celera Diagnostics tests, its ability to sell its products to the clinical diagnostics market will be impaired.

Sales of Celera Diagnostics products will depend, in large part, on the availability of adequate reimbursement to users of those products from government insurance plans, including Medicare and Medicaid in the U.S., managed care organizations, and private insurance plans. Physicians recommendations to use diagnostic tests, as well as decisions by patients to pursue those tests, are likely to be influenced by the availability of reimbursement by insurance companies and other third party payors. Third-party payors are increasingly attempting to contain health care costs by limiting both the extent of coverage and the reimbursement rate for testing and treatment products and services. In particular, products and services that are determined to be investigational in nature or that are not considered reasonably necessary for diagnosis or treatment may be denied reimbursement coverage. In addition, third-party payors are increasingly limiting reimbursement coverage for medical diagnostic products and, in many instances, are exerting pressure on medical suppliers to reduce their prices. Thus, third-party reimbursement may not be consistently available or financially adequate to cover the cost of Celera Diagnostics products. This could limit the ability of Celera Diagnostics to sell its products, cause Celera Diagnostics to reduce the prices of its products, or otherwise adversely affect Celera Diagnostics operating results.

Because each third-party payor individually approves reimbursement, obtaining these approvals is a time-consuming and costly process that requires Celera Diagnostics to provide scientific and clinical support for the use of each of its products to each payor separately with no assurance that such approval will be obtained. This process can delay the broad market introduction of new products and could have a negative effect on Celera Diagnostics revenues and operating results.

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If Celera Diagnostics fails to maintain its existing collaborative relationships and enter into new collaborative relationships, or if collaborators do not perform under collaboration agreements, development of its diagnostic products could be delayed.

Celera Diagnostics strategy for the discovery, development, clinical testing, manufacturing and commercialization of most of its diagnostic product candidates includes entering into collaborations with partners. Although Celera Diagnostics has expended, and continues to expend, time and money on internal research and development programs, it may be unsuccessful in creating diagnostic product candidates that would enable it to form additional collaborations.

Celera Diagnostics has entered into a strategic alliance agreement with Abbott Laboratories for the joint discovery, development, manufacturing, and commercialization of nucleic acid-based diagnostic products. Although this is a long-term alliance, the alliance agreement contains provisions that could result in early termination for reasons that include the following: breach by either company; a change in control of either company; either company s dissatisfaction with the performance of the alliance according to specific timelines for such judgments set forth in the alliance agreement; or by either company if the other party fails to meet performance criteria applicable to the other party set forth in the alliance agreement. In addition, the amount and timing of resources to be devoted to research, development, eventual clinical trials and commercialization activities by Abbott are not within Celera Diagnostics control. Future collaborations with other third parties are likely to be subject to similar terms and conditions. Celera Diagnostics cannot ensure that its collaborators will perform their obligations as expected. If any of Celera Diagnostics collaborators terminate or elect to cancel their agreements or otherwise fail to conduct their collaborative activities in a timely manner, the development or commercialization of diagnostics products may be delayed or otherwise adversely affected. If in some cases Celera Diagnostics assumes responsibilities for continuing programs on its own after termination of a collaboration, Celera Diagnostics may be required to devote additional resources to product development and commercialization or Celera Diagnostics may need to cancel some development programs.

Celera Diagnostics does not have a sales and service capability in the clinical diagnostic market.

Celera Diagnostics currently does not have a sales and service organization. Accordingly, its ability to successfully sell its products will depend on its ability to either develop a sales and service organization, work with Abbott Laboratories under their current agreement, work with another distributor, or a combination of these alternatives. In jurisdictions where Celera Diagnostics uses third party distributors, its success will depend to a great extent on the efforts of the distributors.

Celera Diagnostics has limited manufacturing capability and may encounter difficulties expanding Celera Diagnostics operations.

Celera Diagnostics has limited commercial manufacturing experience and capabilities. If product sales increase, Celera Diagnostics will have to increase the capacity of its manufacturing processes and facilities or rely on its collaborators, if any. Celera Diagnostics may encounter difficulties in scaling-up manufacturing processes and may be unsuccessful in overcoming such difficulties. In such circumstances, Celera Diagnostics ability to meet product demand may be impaired or delayed.

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Celera Diagnostics facilities are subject, on an ongoing basis, to the FDA s Quality System Regulations, international quality standards and other regulatory requirements, including requirements for good manufacturing practices and the State of California Department of Health Services Food and Drug Branch requirements. Celera Diagnostics may encounter difficulties expanding Celera Diagnostics manufacturing operations in accordance with these regulations and standards, which could result in a delay or termination of manufacturing or an inability to meet product demand.

Celera Diagnostics manufacturing operations are located in a facility in Alameda, California. Celera Diagnostics expects to operate its manufacturing out of this facility for the foreseeable future, and it does not have alternative production plans in place or alternative facilities available should its existing manufacturing facility cease to function. Accordingly, Celera Diagnostics business could be adversely affected by unexpected interruptions in manufacturing caused by events such as labor problems, equipment failures, or other factors, and the resulting inability to meet customer orders on a timely basis.

Celera Diagnostics research and product development depends on access to tissue and blood samples from diseased and healthy individuals, other biological materials, and related clinical and other information, which may be in limited supply.

Celera Diagnostics may not be able to obtain or maintain access to these materials and information on acceptable terms, or may not be able to obtain needed consents from individuals providing tissue or blood samples. In addition, government regulation in the U.S. and foreign countries could result in restricted access to, or use of, human tissue or blood samples. If Celera Diagnostics loses access to sufficient numbers or sources of tissue or blood samples, or if tighter restrictions are imposed on its use of the information generated from tissue or blood samples, its business may be harmed.

Single suppliers or a limited number of suppliers provide key components of Celera Diagnostics products. If these suppliers fail to supply these components, Celera Diagnostics may be unable to satisfy product demand.

Several key components of Celera Diagnostics products come from, or are manufactured for Celera Diagnostics by, a single supplier or a limited number of suppliers. This applies in particular to components such as enzymes, florescent dyes, phosphoramadites, and oligonucleotides. Celera Diagnostics acquires some of these and other key components on a purchase-order basis, meaning that the supplier is not required to supply Celera Diagnostics with specified quantities over longer periods of time or set-aside part of its inventory for Celera Diagnostics forecasted requirements. Celera Diagnostics has not arranged for alternative supply sources for some of these components and it may be difficult to find alternative suppliers, especially to replace enzymes and oligonucleotides. Furthermore, in order to maintain compliance with Quality System Regulations, Celera Diagnostics must verify that its suppliers of key components are in compliance with all applicable FDA regulations. Celera Diagnostics believes that compliance with these regulatory requirements would increase the difficulty in arranging for needed alternative supply sources, particularly for components that are from single source suppliers, which means that they are currently the only supplier of custom-ordered components. If Celera Diagnostics product sales increase beyond the forecast levels, or if its suppliers are unable or unwilling to supply it on commercially acceptable terms or comply with regulations applicable to manufacturing of Celera Diagnostics products, it may not have access to sufficient quantities of key components on a timely basis and may be unable to satisfy product demand.

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In addition, if any of the components of Celera Diagnostics products are no longer available in the marketplace, it may be forced to further develop its products or technology to incorporate alternate components. The incorporation of new components into its products may require Celera Diagnostics to seek clearances or approvals from the FDA or foreign regulatory agencies prior to commercialization.

Celera Diagnostics business depends on the continuous, effective, reliable, and secure operation of its computer hardware, software, and Internet applications and related tools and functions.

Celera Diagnostics business requires manipulating and analyzing large amounts of data, and communicating the results of the analysis to its internal research personnel and to its collaborators via the Internet. Also, Celera Diagnostics relies on a global enterprise software system to operate and manage its business. Celera Diagnostics business therefore depends on the continuous, effective, reliable, and secure operation of its computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that Celera Diagnostics hardware or software malfunctions or access to Celera Diagnotics data by Celera Diagnostics internal research personnel or collaborators through the Internet is interrupted, the group s business could suffer. Also, a recent upgrade of our global enterprise software system was performed and we do not believe we will be able to adequately assess the success of the upgrade and the operation of the software until we complete our first quarterly financial close following the upgrade, which close will occur during September 2004. If we encounter difficulties with the upgrade or if we determine that the upgraded software does not operate effectively, these circumstances could interfere with our business operations.

Celera Diagnostics computer and communications hardware is protected through physical and software safeguards. However, it is still vulnerable to fire, storm, flood, power loss, earthquakes, telecommunications failures, physical or software break-ins, software viruses, and similar events. If Celera Diagnostics fails to maintain and further develop the necessary computer capacity and data to support its computational needs, its diagnostic product discovery and research efforts, and Celera Genomics and its collaborators therapeutic products discovery and research efforts, it could experience a loss of or delay in revenues. In addition, any sustained disruption in Internet access provided by third parties could adversely affect Celera Diagnostics business.

Celera Diagnostics competitive position depends on maintaining its intellectual property protection and obtaining licenses to intellectual property it may need from others.

Celera Diagnostics ability to compete and to achieve and maintain profitability depends on its ability to protect its proprietary discoveries and technologies, in large part, through obtaining and enforcing patent rights, maintaining its trade secrets, and operating without infringing the intellectual property rights of others. Celera Diagnostics ability to obtain patent protection for the inventions it makes is uncertain. The patentability of biotechnology inventions involves complex factual and legal questions. As a result, it is difficult to predict whether patents will issue or the breadth of claims that will be allowed in biotechnology and pharmaceutical patents. This may be particularly true with regard to the patenting of gene sequences, gene functions, and genetic variations. In this regard, the U.S. Patent and Trademark Office has adopted guidelines for use in the review of the utility of inventions, particularly biotechnology inventions. These guidelines increased the amount of evidence required to demonstrate utility in order to obtain a patent in the biotechnology field, making patent protection more difficult to obtain. Although others have been successful in obtaining patents to biotechnology inventions, since the adoption of these guidelines, these patents have been issued with increasingly less frequency. As a result, patents may not issue from patent applications that Celera Diagnostics may own or license if the applicant is unable to satisfy the new guidelines.

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In some instances, patent applications in the U.S. are maintained in secrecy until a patent issues. In most instances, the content of U.S. and international patent applications is made available to the public approximately 18 months after the initial filing from which priority is claimed. As a result, Celera Diagnostics cannot be certain that others have not filed patent applications for inventions covered by Celera Diagnostics patent applications or that Celera Diagnostics inventors were the first to make the invention. Accordingly, Celera Diagnostics patent applications may be preempted or Celera Diagnostics may have to participate in interference proceedings before the U.S. Patent and Trademark Office. These proceedings determine the priority of invention and the right to a patent for the claimed invention in the U.S.

Furthermore, lawsuits may be necessary to enforce any patents issued to Celera Diagnostics or to determine the scope and validity of the patent rights of third parties. Lawsuits and interference proceedings, even if they are successful, are expensive to pursue, and Celera Diagnostics could use a substantial amount of its financial resources in either case. An adverse outcome could subject Celera Diagnostics to significant liabilities to third parties and require Celera Diagnostics to license disputed rights from third parties or to cease development or sales of a product.

Celera Diagnostics also relies on trade secret protection for its confidential and proprietary information and procedures. Celera Diagnostics protects its trade secrets through recognized practices, including access control, confidentiality and nonuse agreements with employees, consultants, collaborators and customers, and other security measures. These confidentiality and nonuse agreements may be breached, however, and Celera Diagnostics may not have adequate remedies for a breach. In addition, Celera Diagnostics trade secrets may otherwise become known or be independently developed by competitors. Accordingly, it is uncertain whether Celera Diagnostics reliance on trade secret protection will be adequate to safeguard its confidential and proprietary information and procedures.

Disputes may arise in the future with regard to the ownership of rights to any invention developed with collaborators. These and other possible disagreements with collaborators could lead to delays in the achievement of milestones or receipt of royalty payments or in research, development, and commercialization of Celera Diagnostics products. In addition, these disputes could require or result in lawsuits or arbitration. Lawsuits and arbitration are time-consuming and expensive. Even if Celera Diagnostics wins, the cost of these proceedings could adversely affect its business, financial condition and operating results.

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Celera Diagnostics may infringe the intellectual property rights of third parties and may become involved in expensive intellectual property litigation.

The intellectual property rights of biotechnology companies, including Celera Diagnostics, are generally uncertain and involve complex legal, scientific and factual questions. Celera Diagnostics success in diagnostic discovery and development may depend, in part, on its ability to operate without infringing the intellectual property rights of others and to prevent others from infringing its intellectual property rights.

There has been substantial litigation regarding patents and other intellectual property rights in the biotechnology, pharmaceutical, and diagnostic industries. Celera Diagnostics may become a party to patent litigation or proceedings at the U.S. Patent and Trademark Office to determine its patent rights with respect to third parties. For example, Genetic Technologies Limited has filed a lawsuit against us alleging that we are infringing two of its patents due to the sale of cystic fibrosis reagent kits. In addition, interference proceedings may be necessary to establish which party was the first to make the invention sought to be patented. Also, Celera Diagnostics may become involved in patent litigation against third parties to enforce its patent rights, to invalidate patents held by the third parties, or to defend against these claims. The cost to Celera Diagnostics of any patent litigation or similar proceeding could be substantial, and it may absorb significant management time. If infringement litigation against Celera Diagnostics is resolved unfavorably to Celera Diagnostics, Celera Diagnostics may be enjoined from manufacturing or selling its products or services without a license from a third party. Celera Diagnostics may not be able to obtain a license on commercially acceptable terms, or at all. Similarly, contractual disputes related to existing license rights under third party patents may affect Celera Diagnostics ability to develop, manufacture, and sell its products. For example, existing legal proceedings between Applera Corporation and Roche Molecular Systems, Inc., Hoffmann-LaRoche, Inc., Roche Probe, Inc., and F. Hoffmann-LaRoche, Ltd. may adversely affect the PCR patent rights that Applied Biosystems has contributed to Celera Diagnostics.

Introduction of new products may expose Celera Diagnostics to product liability claims.

New products developed by Celera Diagnostics or its collaborators could expose Celera Diagnostics to potential product liability risks that are inherent in the testing, manufacturing, marketing, and sale of human diagnostic products. In addition, clinicians, patients, third-party payors, and others may at times seek damages based on testing or analysis errors based on a technician s misreading of results, mishandling of the patient samples, or similar claims. Product liability claims or product recalls, regardless of the ultimate outcome, could require Celera Diagnostics to spend significant time and money in litigation and to pay significant damages. Although Celera Diagnostics expects to seek and maintain product liability insurance to cover claims relating to the testing and use of diagnostic products, there can be no assurance that such insurance will be available on commercially reasonable terms, if at all, or that the amount of coverage obtained will be adequate to cover losses from any particular claim.

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The diagnostics industry is intensely competitive and evolving.

There is intense competition among health care, biotechnology, and diagnostic companies attempting to discover candidates for potential new diagnostic products. These companies may:

develop new diagnostic products in advance of Celera Diagnostics or its collaborators;

develop diagnostic products which are more effective or more cost-effective than those developed by Celera Diagnostics or its collaborators;

obtain regulatory clearances or approvals of their diagnostic products more rapidly than Celera Diagnostics or its collaborators; or

obtain patent protection or other intellectual property rights that would limit Celera Diagnostics or its collaborators ability to develop and commercialize, or their customers ability to use, Celera Diagnostics or its collaborators diagnostic products.

Celera Diagnostics competes with companies in the U.S. and abroad that are engaged in the development and commercialization of products and services that provide genetic information. These companies may develop products that are competitive with the products offered by Celera Diagnostics or its collaborators, such as analyte specific reagents or diagnostic test kits that perform the same or similar purposes as Celera Diagnostics or its collaborators products. Also, clinical laboratories may offer testing services that are competitive with the products sold by Celera Diagnostics or its collaborators. For example, a clinical laboratory can use either reagents purchased from manufacturers other than Celera Diagnostics, or use their own internally developed reagents, to make diagnostic tests. If clinical laboratories make tests in this manner for a particular disease, they could offer testing services for that disease as an alternative to products sold by Celera Diagnostics used to test for the same disease. The testing services offered by clinical laboratories may be easier to develop and market than test kits developed by Celera Diagnostics or its collaborators because the testing services are not subject to the same clinical validation requirements that are applicable to FDA-cleared or approved diagnostic test kits. The diagnostic testing services market is dominated by a small number of large clinical testing laboratories, including Laboratory Corporation of America Holdings, Quest Diagnostics Inc., and Specialty Laboratories, Inc.

Also, a substantial portion of all sales of diagnostic products are made to a small number of clinical reference laboratories, including those identified above, and therefore Celera Diagnostics expects to rely on these laboratories for a substantial portion of its sales. Celera Diagnostics inability to establish or maintain one or more of these laboratories as a customer could adversely affect its business, financial condition, and operating results.

Earthquakes could disrupt operations in California.

The headquarters and principal operations of Celera Diagnostics are located in Alameda, California, and Celera Diagnostics has manufacturing facilities in Foster City, California. Alameda and Foster City are located near major California earthquake faults. The ultimate impact of earthquakes on Celera Diagnostics, its significant suppliers, and the general infrastructure is unknown, but operating results could be materially affected in the event of a major earthquake.

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Risks Relating to a Capital Structure with Two Separate Classes of Common Stock

Stockholders of Applera Corporation are stockholders of one company and, therefore, financial effects on one group could adversely affect the other.

Applied Biosystems and Celera Genomics are not separate legal entities. As a result, stockholders will continue to be subject to all of the risks of an investment in Applera Corporation, including Applied Biosystems and Celera Genomics. The risks and uncertainties that may affect the operations, performance, development, and results of the businesses of Applied Biosystems and Celera Genomics are described above. The assets attributed to one group could be subject to the liabilities of the other group, even if these liabilities arise from lawsuits, contracts, or indebtedness that we attribute to the other group. If we are unable to satisfy one group s liabilities out of the assets attributed to it, we may be required to satisfy those liabilities with assets attributed to the other group.

Financial effects from one group that affect our consolidated results of operations or financial condition could, if significant, affect the results of operations or financial condition of the other group and the market price of the common stock relating to the other group. In addition, net losses of either group and dividends or distributions on, or repurchases of, either class of common stock or repurchases of preferred stock will reduce the funds we can pay as dividends on each class of common stock under Delaware law. For these reasons, stockholders should read the consolidated financial information with the financial information we provide for each group.

The market price of either class of our common stock may not reflect the separate performance of the group related to that common stock.

The market price of Applera-Applied Biosystems stock and Applera-Celera stock may not reflect the separate performance of the business of the group relating to that class of common stock. The market price of either class of common stock could simply reflect our performance as a whole, or the market price of either class of common stock could move independently of the performance of the business of either group. Investors may discount the value of either class of common stock because it is part of a common enterprise rather than a stand-alone company.

The market price of either class of our common stock may be affected by factors that do not affect traditional common stock.

The complex nature of the terms of Applera-Applied Biosystems stock and Applera-Celera stock may adversely affect the market price of either class of common stock. The complex nature of the terms of the two classes of common stock, such as the convertibility of Applera-Applied Biosystems stock into Applera-Celera stock, or vice versa, and the potential difficulties investors may have understanding these terms, may adversely affect the market price of either class of common stock.

The market price of Applera-Applied Biosystems stock or Applera-Celera stock may be adversely affected by the fact that holders have limited legal interests in the group relating to the class of common stock held as a separate legal entity. For example, as described in greater detail in the subsequent risk factors, holders of either class of common stock generally do not have separate class voting rights with respect to significant matters affecting either group. In addition, upon our liquidation or dissolution, holders of either class of common stock will not have specific rights to the assets of the group relating to the class of common stock held and will not be entitled to receive proceeds that are proportional to the relative performance of that group.

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The market price of Applera-Applied Biosystems stock or Applera-Celera stock may be adversely affected by events involving the group relating to the other class of common stock or the performance of the class of common stock relating to that group. Events, such as earnings announcements or other developments concerning one group that the market does not view favorably and which thus adversely affect the market price of the class of common stock relating to that group, may adversely affect the market price of the class of common stock relating to the other group. Because both classes of common stock are common stock of Applera Corporation, an adverse market reaction to one class of common stock may, by association, cause an adverse reaction to the other class of common stock. This reaction may occur even if the triggering event was not material to us as a whole.

Limits exist on the voting power of group common stock.

Applera-Celera stock may not have any influence on the outcome of stockholder voting. Applera-Applied Biosystems stock currently has a substantial majority of the voting power of our common stock and had approximately 82.6% of the voting power as of August 30, 2004, the record date for our 2004 annual meeting of stockholders. Except in limited circumstances where there is separate class voting, the relative voting power of the two classes of common stock fluctuates based on their relative market values. Therefore, except in cases of separate class voting, either class of common stock that is entitled to more than the number of votes required to approve any stockholder action could control the outcome of the vote even if the matter involves a divergence or conflict of the interests of the holders of Applera-Applied Biosystems stock and Applera-Celera stock. These matters may include mergers and other extraordinary transactions.

A class of group common stock with less than majority voting power can block action if a class vote is required. If Delaware law, stock exchange rules, or our Board of Directors requires a separate vote on a matter by the holders of either Applera-Applied Biosystems stock or Applera-Celera stock, those holders could prevent approval of the matter even if the holders of a majority of the total number of votes cast or entitled to be cast, voting together as a class, were to vote in favor of it. As a result, in cases where holders of Applera-Applied Biosystems stock or Applera-Celera stock vote as separate classes on a proposal, the affirmative vote of shares representing a majority of one class of common stock will not prevent the holders of the other class of common stock from defeating the proposal.

Holders of only one class of common stock cannot ensure that their voting power will be sufficient to protect their interests. Since the relative voting power per share of Applera-Applied Biosystems stock and Applera-Celera stock will fluctuate based on the market values of the two classes of common stock, the relative voting power of a class of common stock could decrease. As a result, holders of shares of only one of the two classes of common stock cannot ensure that their voting power will be sufficient to protect their interests.

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Stockholders of either class of common stock will not have some of the stockholder rights traditionally associated with common stock. Neither Applied Biosystems nor Celera Genomics will have a separate board of directors to represent solely the interests of either class of common stock as holders of that class. Consequently, there will be no board of directors that owes any separate duties to holders of one class of common stock as holders of that class. Our Board of Directors will act in accordance with its good faith business judgment of our best interests, taking into consideration the interests of all common stockholders regardless of class or series, which may be detrimental to holders of one class of common stock has holders of that class.

Stockholders may not have any remedies for breach of fiduciary duties if any action by directors or officers has a disadvantageous effect on either class of common stock.

Stockholders may not have any remedies if any action or decision of our Board of Directors or officers has a disadvantageous effect on Applera-Applied Biosystems stock or Applera-Celera stock compared to the other class of common stock. Cases in Delaware involving tracking stocks have established that decisions by directors or officers involving differing treatment of tracking stocks are judged under the principle known as the business judgment rule unless self-interest is shown.

In addition, principles of Delaware law established in cases involving differing treatment of two classes of common stock or two groups of holders of the same class of common stock provide that a board of directors owes an equal duty to all stockholders regardless of class or series. Absent abuse of discretion, a good faith business decision made by a disinterested and adequately informed Applera Corporation Board of Directors, Board of Directors committee, or officer with respect to any matter having different effects on holders of Applera-Applied Biosystems stock and holders of Applera-Celera stock would be a defense to any challenge to the determination made by or on behalf of the holders of either class of common stock.

Stock ownership could cause directors and officers to favor one group over the other.

As a policy, our Board of Directors periodically monitors the ownership of shares of Applera-Applied Biosystems stock and Applera-Celera stock by our directors and senior officers as well as their option holdings and other benefits so that their interests are not misaligned with the two classes of common stock and with their duty to act in the best interests of us and our stockholders as a whole. However, because the actual stock market value of their interests in Applera-Applied Biosystems stock and Applera-Celera stock could vary significantly, it is possible that they could favor one group over the other as a result of their common stock holdings, options and other benefits. As of August 30, 2004, our directors and executive officers held shares of Applera-Applied Biosystems stock and Applera-Celera stock representing approximately equal percentages of the total shares outstanding of Applera-Applied Biosystems stock and Applera-Celera stock. The stock market value of these shares will vary with fluctuations in the market price of Applera-Applied Biosystems stock and Applera-Celera stock. However, the market capitalization of Applied Biosystems is substantially greater than that of Celera Genomics and, therefore, the market value of Applera-Applied Biosystems stock held by our directors and senior officers was significantly higher than the market value of Applera-Celera stock held by them on that date.

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Numerous potential conflicts of interest exist between the classes of common stock that may be difficult to resolve by our Board of Directors or that may be resolved adversely to one of the classes.

Allocation of corporate opportunities could favor one group over the other. Our Board of Directors may be required to allocate corporate opportunities between Applied Biosystems and Celera Genomics. In some cases, our directors could determine that a corporate opportunity, such as a business that we are acquiring or a new business, should be shared by the groups or be allocated to one group over the other. Any decisions could favor one group to the detriment of the other.

Applied Biosystems and Celera Genomics may compete with each other to the detriment of their businesses. The existence of two separate classes of common stock will not prevent Applied Biosystems and Celera Genomics from competing with each other. Any competition between Applied Biosystems and Celera Genomics could be detrimental to the businesses of either or both of the groups. Under a Board of Directors policy, the groups will generally not engage in the principal businesses of the other, except for joint transactions with each other. However, our Chief Executive Officer or Board of Directors will permit indirect competition between the groups, such as one group doing business with a competitor of the other group, based on his or its good faith business judgment that the competition is in our best interests and the best interests of all of our stockholders as a whole. In addition, the groups may compete in a business that is not a principal business of the other group.

Our Board of Directors may pay more or less dividends on group common stock than if that group were a separate company. Subject to the limitations referred to below, our Board of Directors has the authority to declare and pay dividends on Applera-Applied Biosystems stock and Applera-Celera stock in any amount and could, in its sole discretion, declare and pay dividends exclusively on Applera-Applied Biosystems stock, exclusively on Applera-Celera stock, or on both, in equal or unequal amounts. Our Board of Directors is not required to consider the amount of dividends previously declared on each class, the respective voting or liquidation rights of each class, or any other factor. The performance of one group may cause our Board of Directors to pay more or less dividends on the common stock relating to the other group than if that other group were a stand-alone company. In addition, Delaware law and our certificate of incorporation impose limitations on the amount of dividends that may be paid on each class of common stock.

Proceeds of mergers or consolidations may be allocated unfavorably. Our Board of Directors will determine how consideration to be received by holders of common stock in connection with a merger or consolidation involving us is to be allocated among holders of each class of common stock. This percentage may be materially more or less than that which might have been allocated to the holders had our Board of Directors chosen a different method of allocation.

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Holders of either class of common stock may be adversely affected by a conversion of group common stock. Our Board of Directors could, in its sole discretion and without stockholder approval, determine to convert shares of Applera-Applied Biosystems stock into shares of Applera-Celera stock, or vice versa, at any time, including when either or both classes of common stock may be considered to be overvalued or undervalued. If our Board of Directors chose to issue Applera-Celera stock in exchange for Applera-Applied Biosystems stock, or vice versa, the conversion would dilute the interests in us of the holders of the class of common stock being issued in the conversion. If our Board of Directors were to choose to issue Applera-Celera stock in exchange for Applera-Applied Biosystems stock, or vice versa, the conversion could give holders of shares of the class of common stock being converted a greater or lesser premium than any premium that was paid or might be paid by a third-party buyer of all or substantially all of the assets of the group whose stock is converted.

Cash proceeds of newly issued Applera-Celera stock in the future could be allocated to Applied Biosystems. If and to the extent Applied Biosystems holds Celera Genomics Designated Shares at the time of any future sale of Applera-Celera stock, our Board of Directors could allocate some or all of the proceeds of that sale to Applied Biosystems in consideration of a reduction in the number of these shares. Celera Genomics Designated Shares are a type of authorized shares of Applera-Celera stock. Any decision could favor one group over the other group. For example, the decision to allocate the proceeds of that sale to Applied Biosystems could adversely affect Celera Genomics ability to obtain funds to finance its growth strategies. Applied Biosystems does not hold any Celera Genomics Designated Shares as of the date of this report. Celera Genomics Designated Shares could be issued in the future if our Board of Directors determines that Celera Genomics requires additional capital to finance its business and that Applied Biosystems should supply that capital.

Our Board of Directors may change its management and allocation policies without stockholder approval to the detriment of either group.

Our Board of Directors may modify or rescind our policies with respect to the allocation of corporate overhead, taxes, debt, interest, and other matters, or may adopt additional policies, in its sole discretion without stockholder approval. A decision to modify or rescind these policies, or adopt additional policies, could have different effects on holders of Applera-Applied Biosystems stock and holders of Applera-Celera stock or could result in a benefit or detriment to one class of stockholders compared to the other class. Our Board of Directors will make any decision in accordance with its good faith business judgment that the decision is in our best interests and the best interests of all of our stockholders as a whole.

Either Applied Biosystems or Celera Genomics may finance the other group on terms unfavorable to either group.

From time to time, we anticipate that we will transfer cash and other property between groups to finance their business activities. When this occurs, the group providing the financing will be subject to the risks relating to the group receiving the financing. We will account for those transfers in one of the following ways:

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as a reallocation of pooled debt or preferred stock;

as a short-term or long-term loan between groups or as a repayment of a previous borrowing;

as an increase or decrease in Celera Genomics Designated Shares; or

as a sale of assets between groups.

Our Board of Directors has not adopted specific criteria for determining when it will account for the transfer of cash or other property as a reallocation of pooled debt or preferred stock, a loan or repayment, an increase or decrease in Celera Genomics Designated Shares, or a sale of assets. These determinations, including the terms of any transactions accounted for as debt, may be unfavorable to either the group transferring or receiving the cash or other property. Our Board of Directors expects to make these determinations, either in specific instances or by setting generally applicable policies, after considering the financing requirements and objectives of the receiving group, the investment objectives of the transferring group, and the availability, cost, and time associated with alternative financing sources, prevailing interest rates, and general economic conditions.

We cannot assure stockholders that any terms that we fix for debt will approximate those that could have been obtained by the borrowing group if it were a stand-alone company.

Celera Genomics could incur a higher tax liability than if it were a stand-alone taxpayer.

Our tax allocation policy provides that some tax benefits that cannot be used by the group generating those benefits but can be used on a consolidated basis are to be transferred, without reimbursement, to the group that can use the benefits. Any tax benefits that are transferred from Celera Genomics to Applied Biosystems will not be carried forward to reduce Celera Genomics future tax liability. As a result of this policy, Celera Genomics generated tax benefits of $19.0 million in our 2002 fiscal year, $28.1 million in our 2003 fiscal year, and $12.3 million in our 2004 fiscal year that were utilized by Applied Biosystems with no reimbursement to Celera Genomics. This and future use by Applied Biosystems, without reimbursement, of tax benefits generated by Celera Genomics could result in Celera Genomics paying a greater portion of the total corporate tax liability over time than would have been the case if Celera Genomics were a stand-alone taxpayer.

Holders of group common stock may receive less consideration upon a sale of assets than if the group were a separate company.

Our certificate of incorporation provides that if a disposition of all or substantially all of the assets of either group occurs, we must, subject to some exceptions:

distribute to holders of the class of common stock relating to that group an amount equal to the net proceeds of such disposition; or

convert at a 10% premium the common stock relating to that group into shares of the class of common stock relating to the other group.

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If the group subject to the disposition were a separate, independent company and its shares were acquired by another person, some of the costs of that disposition, including corporate level taxes, might not be payable in connection with that acquisition. As a result, if the group subject to the disposition were a stand-alone company, stockholders of that group might receive a greater amount than the net proceeds that would be received by those stockholders if the assets of that group were sold and the proceeds distributed to those stockholders. In addition, we cannot assure stockholders that the net proceeds per share of the common stock relating to that group will be equal to or more than the market value per share of that common stock prior to or after announcement of a disposition.

Our capital structure and variable vote per share may discourage acquisitions of a group or a class of common stock.

A potential acquirer could acquire control of us by acquiring shares of common stock having a majority of the voting power of all shares of common stock outstanding. This majority could be obtained by acquiring a sufficient number of shares of both classes of common stock or, if one class of common stock has a majority of the voting power, only shares of that class since the relative aggregate voting power of the two classes of common stock fluctuates based on their relative aggregate market values. Currently, Applera-Applied Biosystems stock has a substantial majority of the voting power. As a result, it might be possible for an acquirer to obtain control by purchasing only shares of Applera-Applied Biosystems stock.

Decisions by our Board of Directors and officers that affect market values could adversely affect voting and conversion rights.

The relative voting power per share of each class of common stock and the number of shares of one class of common stock issuable upon the conversion of the other class of common stock will vary depending upon the relative market values of Applera-Applied Biosystems stock and Applera-Celera stock. The market value of either or both classes of common stock could be adversely affected by market reaction to decisions by our Board of Directors or management that investors perceive as affecting differently one class of common stock compared to the other. These decisions could involve changes to our management and allocation policies, transfers of assets between groups, allocations of corporate opportunities and financing resources between groups, and changes in dividend policies.

Provisions governing common stock could discourage a change of control and the payment of a premium for stockholders shares.

Our stockholder rights plan could prevent stockholders from profiting from an increase in the market value of their shares as a result of a change in control of us by delaying or preventing a change in control. The existence of two classes of common stock could also present complexities and may pose obstacles, financial and otherwise, to an acquiring person. In addition, provisions of Delaware law and our certificate of incorporation and bylaws may also deter hostile takeover attempts.

Item 6. Selected Financial Data

We incorporate herein by reference pages 17 and 18 of our 2004 Annual Report.

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

We incorporate herein by reference pages 19 through 40 of our 2004 Annual Report. However, we note that the statements contained under the heading Outlook on pages 38 through 40 of our 2004 Annual Report were made as of the date of our 2004 Annual Report. Our incorporation of those statements into this report does not constitute, and should not be read as, an affirmation or republication of those statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We incorporate herein by reference page 38 of our 2004 Annual Report.

Item 8. Financial Statements and Supplementary Data

The following financial statements and the supplementary financial information included in our 2004 Annual Report are incorporated herein by reference: the Consolidated Financial Statements and the report thereon of PricewaterhouseCoopers LLP dated July 28, 2004, on pages 41 through 86 of our 2004 Annual Report, including Note 12, page 71, which contains unaudited quarterly financial information.

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that the information required to be disclosed in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of these disclosure controls and procedures as of the end of our 2004 fiscal year, the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to achieve their stated purpose. However, there is no assurance that our disclosure controls and procedures will operate effectively under all circumstances.

Internal Control Over Financial Reporting

No changes were made to our internal control over financial reporting during the fourth fiscal quarter of our 2004 fiscal year that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

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PART III

Item 10. Directors and Executive Officers of the Registrant

Identification and Business Experience of Directors

With respect to the identification and business experience of our directors and persons nominated to become directors, we incorporate herein by reference the information contained in our 2004 Proxy Statement under the heading Proposal 1 Election of Directors.

Identification and Business Experience of Executive Officers

The following is a list of our executive officers, identifying as of September 9, 2004, their: ages; corporate offices presently held and year first elected to those offices; and other positions currently held.

Name	Age	Present Corporate Offices (Year First Elected)	Other Positions Currently Held
Robert F.G. Booth	50	Vice President (2002)	Chief Scientific Officer, Celera Genomics Group
Catherine M. Burzik	53	Senior Vice President, and President, Applied Biosystems Group (2004)	Not applicable
Ugo D. DeBlasi	42	Vice President and Controller (2003)	Not applicable
Vikram Jog	48	Vice President (2003)	Vice President, Finance, Celera Genomics and Celera Diagnostics
Barbara J. Kerr	58	Vice President, Human Resources (2000)	Not applicable
Sandeep Nayyar	44	Assistant Controller (2002)	Vice President, Finance, Applied Biosystems Group
Kathy P. Ordoñez	53	Senior Vice President, and President, Celera Genomics Group and Celera Diagnostics (2002)	Not applicable
William B. Sawch	49	Senior Vice President (1997) and General Counsel (1993)	Not applicable
Tony L. White	58	Chairman, President, and Chief Executive Officer (1995)	Not applicable
Dennis L. Winger	56	Senior Vice President and Chief Financial Officer (1997)	Not applicable

Each of the executive officers identified above was most recently elected to the corporate offices identified above by our Board of Directors in August 2004. The term of each officer will continue until their successors have been duly elected or, if earlier, their death, resignation, or removal. Each of the executive officers has been employed by us or a subsidiary in one or more executive or managerial capacities for at least the past five years, with the exception of Dr. Booth, Ms. Burzik, Ms. Kerr, Mr. Nayyar, and Ms. Ordoñez.

Dr. Booth was elected Vice President on August 15, 2002. Prior to our employment of him in August 2002, Dr. Booth was employed by Hoffmann-La Roche, a leading international healthcare company, where he held a series of executive positions over 13 years, including most recently as Senior Vice President responsible for all research and early development of inflammatory, viral, respiratory, and bone disease products from January 1996 to August 2002.

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Ms. Burzik was first elected as Vice President on September 2, 2003, and was elected to her current position of Senior Vice President, and President, Applied Biosystems Group, on August 20, 2004. Prior to our employment of her in September 2003, she was employed by Johnson & Johnson, a leading international provider of health care products, where she was President of its Ortho-Clinical Diagnostics, Inc. subsidiary from 1998 to 2003, and General Manager of its Critikon, Inc. business from 1997 to 1998. Prior to that, Ms. Burzik was employed by Eastman Kodak Company, a leading international provider of imaging products and services, where she held various operations and marketing positions over 20 years. These positions included most recently Vice President, Corporate Marketing from 1996 to 1997, and Chief Executive Officer and President of its former subsidiary Kodak Health Imaging Systems, Inc.

Ms. Kerr was elected Vice President, Human Resources on September 5, 2000. Prior to our employment of her in September 2000, Ms. Kerr served as a principal of iQuantic, Inc., a human resources and compensation consulting firm. Prior to that, Ms. Kerr was employed by Chiron Corporation, which conducts research and development in the fields of biological proteins, gene therapy, and combinatorial chemistry, where she was Vice President, Human Resources from 1990 to 1997.

Mr. Nayyar was elected Assistant Controller on April 5, 2002. Prior to our employment of him in October 2001, Mr. Nayyar was employed by Quantum Corporation, a data storage company, where he was Vice President of Finance for the Hard Disk Drive Group from 2000 to 2001, Vice President, Finance for the High-end Storage Division from 1998 to 2000, Director of Finance for the Corporate Finance Group from 1997 to 1998, and Controller for the High Capacity Storage Group from 1994 to 1997.

Ms. Ordoñez was first elected to serve as a corporate officer on December 1, 2000, and was elected to her current position of Senior Vice President, and President, Celera Genomics Group and Celera Diagnostics on August 15, 2002. Prior to our employment of her in December 2000, Ms. Ordoñez was employed by Hoffmann-La Roche, a leading international healthcare company, where she was President and Chief Executive Officer of Roche Molecular Systems from 1991 to 2000.

Family Relationships

To the best of our knowledge and belief, there is no family relationship between any of our directors, executive officers, or persons nominated or chosen by us to become a director or an executive officer.

Involvement in Certain Legal Proceedings

To the best of our knowledge and belief, none of our directors, persons nominated to become directors, or executive officers has been involved in any proceedings during the past five years that are material to an evaluation of the ability or integrity of such persons to be our directors or executive officers.

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Audit Committee and Audit Committee Financial Expert

We have a separately designated standing audit committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934. We have named that committee our Audit/Finance Committee. The members of that committee as of the date of this report are Richard H. Ayers (co-chairman), Robert H. Hayes, Theodore E. Martin (co-chairman), and James R. Tobin. Our Board of Directors has determined that our Audit/Finance Committee has three audit committee financial experts as that term has been defined by the Securities and Exchange Commission in Item 401(h) of its Regulation S-K, including all of its members except for Robert H. Hayes. The designation of members of our Audit/Finance Committee as audit committee financial experts does not impose on those members any duties, obligations, or liabilities that are greater than are generally imposed on them as members of our Audit/Finance Committee and Board of Directors, and does not affect the duties, obligations, or liabilities of any other member of our Audit/Finance Committee or Board of Directors. All of the members of our Audit/Finance Committee, including those that our Board of Directors have determined are audit committee financial experts, are independent as that term has been defined by the SEC in Item 7(d)(3)(iv) of Schedule 14A. Additional information regarding our Audit/Finance Committee is incorporated by reference to the information contained in our 2004 Proxy Statement under the headings Board of Directors and Committees Audit/Finance Committee.

Recommendation of Nominees to our Board of Directors

Information concerning our procedures by which security holders may recommend nominees to our Board of Directors is incorporated herein by reference to the information contained in our 2004 Proxy Statement under the headings Board of Directors and Committees Board Committees Nominating/Corporate Governance Committee.

Section 16(a) Beneficial Ownership Reporting Compliance

Information concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated herein by reference to the information contained in our 2004 Proxy Statement under the headings Ownership of Company Stock Section 16(a) Beneficial Ownership Reporting Compliance.

Code of Ethics

We have adopted a code of ethics that applies to our officers, directors, and employees. Our code of ethics, which we refer to as our Code of Business Conduct and Ethics, was designed to comply with the definition of code of ethics adopted by the Securities and Exchange Commission as applicable to our Chief Executive Officer (our principal executive officer), our Chief Financial Officer (our principal financial officer), and our Controller (our principal accounting officer). This definition is contained in Item 406(b) of the SEC s Regulation S-K. Our code of ethics was also designed to meet the code of business conduct and ethics requirements promulgated by the New York Stock Exchange, which requirements are set forth in Section 303A.10 of the NYSE Listed Company Manual.

Our Code of Business Conduct and Ethics is posted on our Applera, Applied Biosystems, and Celera Genomics Internet websites. Also, we intend to post any amendments to or waivers from the code that are applicable to our officers or directors on these Internet websites as

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required to satisfy SEC and New York Stock Exchange disclosure requirements applicable to amendments and waivers. This information can be accessed on our websites free of charge as described in Part I of this report on page 2 under the headings Company Overview Available Information. In addition, you can obtain this information free of charge by calling our corporate Secretary at 203-840-2000 or by making a request in writing mailed to: Applera Corporation, Attention: Secretary, Applera Corporation, 301 Merritt 7, P.O. Box 5435, Norwalk, CT 06856-5435.

Item 11. Executive Compensation

We incorporate herein by reference the information contained in our 2004 Proxy Statement under the heading Executive Compensation.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Securities Authorized for Issuance Under Equity Compensation Plans

Information concerning securities authorized for issuance under equity compensation plans as of the end of our 2004 fiscal year is incorporated herein by reference to the information contained in our 2004 Proxy Statement under the headings Proposals 4 and 5 Approval of the Applera Corporation/Applied Biosystems Group Amended and Restated 1999 Stock Incentive Plan and the Applera Corporation/Celera Genomics Group Amended and Restated 1999 Stock Incentive Plan Equity Compensation Plan Information.

Security Ownership of Certain Beneficial Owners

Information concerning the security ownership of certain beneficial owners is incorporated herein by reference to the information contained in our 2004 Proxy Statement under the headings Ownership of Company Stock Greater than 5% Beneficial Owners.

Security Ownership of Management

Information concerning the security ownership of management is incorporated herein by reference to the information contained in our 2004 Proxy Statement under the headings Ownership of Company Stock Directors and Executive Officers.

Changes in Control

We know of no arrangements, including any pledge by any person of our securities, the operation of which may at a subsequent date result in a change in control of Applera.

Item 13. Certain Relationships and Related Transactions

Information concerning certain relationships and related transactions is incorporated herein by reference to the information contained in our 2004 Proxy Statement under the headings Executive Compensatin Employment Agreements and Other Relationships.

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Item 14. Principal Accountant Fees and Services

Information concerning fees billed by PricewaterhouseCoopers LLP, our independent registered public accounting firm, during our 2003 and 2004 fiscal years, and information concerning the pre-approval policies and procedures of the Audit/Finance Committee of our Board of Directors, is incorporated herein by reference to the information contained in our 2004 Proxy Statement under the heading Proposal 2 Ratification of the Selection of Independent Registered Public Accounting Firm.

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(a) 1. Financial Statements

The following financial statements, together with the report thereon of PricewaterhouseCoopers LLP dated July 28, 2004, appearing in our 2004 Annual Report, are incorporated by reference in this report. With the exception of the aforementioned information and that which is specifically incorporated in Parts I and II of this report, our 2004 Annual Report is not to be deemed filed as part of this report.

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(a) 2. Financial Statement Schedule

The following additional financial data should be read in conjunction with the consolidated financial statements in our 2004 Annual Report. Schedules not included with this additional financial data have been omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(a) 3. Exhibits

Exhibit No.	
2.1	Agreement and Plan of Merger dated March 10, 1999, among The Perkin-Elmer Corporation, a New York corporation, The Perkin-Elmer Corporation, a Delaware corporation, and PE Merger Corp., a New York corporation (incorporated by reference to Exhibit 2.1 to our Registration Statement on Form S-4 (No. 333-67797)).
2.2	Agreement and Plan of Merger dated as of June 12, 2001, among Applera Corporation, a Delaware corporation, Angel Acquisition Sub, Inc., a Delaware corporation, and Axys Pharmaceuticals, Inc., a Delaware corporation (incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K dated June 12, 2001 (Commission file number 1-4389)).
3.1.1	Restated Certificate of Incorporation of Applera (incorporated by reference to Exhibit 3(i) to our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2000 (Commission file number 1-4389)).
3.1.2	Certificate of Designations of Series A Participating Junior Preferred Stock and Series B Participating Junior Preferred Stock (incorporated by reference to Exhibit A to Exhibit 4.1 to our Registration Statement on Form S-4 (No. 333-67797)).
3.2	By-laws of Applera (incorporated by reference to Exhibit 3.2 to our Registration Statement on Form S-4 (No. 333-67797)).
4.1	Stockholder Protection Rights Agreement dated as of April 28, 1999, between Applera and BankBoston, N.A. (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-4 (No. 333-67797)).
4.2	Amendment to Rights Agreement dated as of April 17, 2002, among BankBoston, N.A., EquiServe Trust Company, N.A., and Applera (incorporated by reference to Exhibit 4.2 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2002 (Commission file number 1-4389)).
4.3	Credit Agreement dated as of April 20, 2000, among The Perkin-Elmer Corporation, Applera, the lenders party thereto, Salomon Smith Barney Inc., Wachovia Bank, N.A., The Chase Manhattan Bank, and Citibank, N.A. (incorporated by reference to Exhibit 4(2) to our Annual Report on Form 10-K for the fiscal year ended June 30, 2000 (Commission file number 1-4389)).
4.4	Letter dated February 5, 2003, from Applera to Citibank, N.A. regarding the Credit Agreement dated as of April 20, 2000 (incorporated by reference to Exhibit 4.4 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2003 (Commission file number 1-4389)).
4.5	Indenture dated as of September 22, 2000, between U.S. Bank Trust National Association and Axys Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K of Axys Pharmaceuticals, Inc. filed September 28, 2000 (Commission file number 0-22788)).

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4.6	First Supplemental Indenture dated as of September 22, 2000, between U.S. Bank Trust National Association and Axys Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K of Axys Pharmaceuticals, Inc. filed September 28, 2000 (Commission file number 0-22788)).
10.1	The Perkin-Elmer Corporation 1993 Stock Incentive Plan for Key Employees (incorporated by reference to Exhibit 99 to our Registration Statement on Form S-8 (No. 33-50847)).*
10.2	The Perkin-Elmer Corporation 1996 Stock Incentive Plan (incorporated by reference to Exhibit 99 to our Registration Statement on Form S-8 (No. 333-15189)).*
10.3	The Perkin-Elmer Corporation 1996 Employee Stock Purchase Plan, as amended October 15, 1998 (incorporated by reference to Exhibit A to our Proxy Statement for our 1998 Annual Meeting of Stockholders (Commission file number 1-4389)).*
10.4	The Perkin-Elmer Corporation 1997 Stock Incentive Plan (incorporated by reference to Exhibit 99 to our Registration Statement on Form S-8 (No. 333-38713)).*
10.5	The Perkin-Elmer Corporation 1998 Stock Incentive Plan (incorporated by reference to Exhibit B to our Proxy Statement for our 1998 Annual Meeting of Stockholders (Commission file number 1-4389)).*
10.6	Applera Corporation 1999 Employee Stock Purchase Plan, as amended October 17, 2002 (incorporated by reference to Appendix A to Schedule 14A, filed September 6, 2002, containing our Proxy Statement for our 2002 Annual Meeting of Stockholders (Commission file number 1-4389)).*
10.7	Applera Corporation/Applied Biosystems Group 1999 Stock Incentive Plan, as amended through August 21, 2003 (incorporated by reference to Exhibit 10.7 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2003 (Commission file number 1-4389)).*
10.8	Applera Corporation/Celera Genomics Group 1999 Stock Incentive Plan, as amended through August 21, 2003 (incorporated by reference to Exhibit 10.8 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2003 (Commission file number 1-4389)).*
10.9	The Perkin-Elmer Corporation Supplemental Retirement Plan effective as of August 1, 1979, as amended through October 1, 1996 (incorporated by reference to Exhibit 10(22) to our Annual Report on Form 10-K for the fiscal year ended June 30, 2000 (Commission file number 1-4389)).*
10.10	The Excess Benefit Plan of Applera Corporation, as amended and restated effective July 1, 2004.*
10.11	1993 Director Stock Purchase and Deferred Compensation Plan, as amended through March 17, 2000 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2000 (Commission file number 1-4389)).*
10.12	Applera Corporation Performance Unit Bonus Plan, as amended through August 21, 2003 (incorporated by reference to Exhibit 10.14 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2003 (Commission file number 1-4389)).*
10.13	The Estate Enhancement Plan of The Perkin-Elmer Corporation (incorporated by reference to Exhibit 10(22) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1997 (Commission file number 1-4389)).*
10.14	Applera Corporation Deferred Compensation Plan, as amended and restated effective as of January 1, 2002 (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended December 31, 2001 (Commission file number 1-4389)).*
10.15	PerSeptive Biosystems, Inc. 1992 Stock Plan, as amended January 20, 1997 (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of PerSeptive Biosystems, Inc. for the fiscal quarter ended March 29, 1997 (Commission file No. 0-20032)).*
10.16	PerSeptive Biosystems, Inc. 1997 Non-Qualified Stock Option Plan, as amended August 21, 1997 (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 of PerSeptive Biosystems, Inc. (No. 333-38989)).*

10.17	Molecular Informatics, Inc. 1997 Equity Ownership Plan (incorporated by reference to Exhibit 99 to our Registration Statement on Form S-8 (No. 333-42683)).*
10.18	Paracel, Inc. Stock Option Plan (incorporated by reference to Exhibit 10.22 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2002 (Commission file number 1-4389)).*
10.19	Axys Pharmaceuticals, Inc. 1989 Stock Plan, as amended through May 21, 1997 (incorporated by reference to Exhibit 10.2 to Annual Report on Form 10-K of Axys Pharmaceuticals, Inc. for the fiscal year ended December 31, 1996 (Commission file number 0-22788)). *

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10.20	Axys Pharmaceuticals, Inc. 1997 Equity Incentive Plan, as amended through May 14, 2001 (incorporated by reference to Exhibit 10.30 to our Registration Statement on Form S-8 (No. 333-73980)).*
10.21	Axys Pharmaceuticals, Inc. 1997 Non-Officer Equity Incentive Plan, as amended through October 16, 1998 (incorporated by reference to Exhibit 10.31 to our Registration Statement on Form S-8 (No. 33-73980)).*
10.22	Employment Agreement dated as of September 12, 1995, between Applera and Tony L. White (incorporated by reference to Exhibit 10(21) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1995 (Commission file number 1-4389)).*
10.23	Amendment dated August 17, 2001, to Employment Agreement dated as of September 12, 1995, between Applera and Tony L. White (incorporated by reference to Exhibit 10.l4 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2001 (Commission file number 1-4389)).*
10.24	Change of Control Agreement dated as of September 12, 1995, between Applera and Tony L. White (incorporated by reference to Exhibit 10(16) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1995 (Commission file number 1-4389)).*
10.25	Employment Agreement dated as of November 16, 1995, between Applera and Michael W. Hunkapiller (incorporated by reference to Exhibit 10(11) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1996 (Commission file number 1-4389)).*
10.26	Deferred Compensation Contract dated as of September 15, 1994, between Applera and Michael W. Hunkapiller (incorporated by reference to Exhibit 10(7) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1995 (Commission file number 1-4389)).*
10.27	Employment Agreement dated as of November 16, 1995, between Applera and William B. Sawch (incorporated by reference to Exhibit 10(16) to our Annual Report on Form 10-K for fiscal year ended June 30, 1998 (Commission file number 1-4389)).*
10.28	Deferred Compensation Contract dated as of July 15, 1993, between Applera and William B. Sawch (incorporated by reference to Exhibit 10(19) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1998 (Commission file number 1-4389)).*
10.29	Letter Agreement dated June 24, 1997, between Applera and Dennis L. Winger (incorporated by reference to Exhibit 10(18) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1998 (Commission file number 1-4389)) *
10.30	Employment Agreement dated as of September 25, 1997, between Applera and Dennis L. Winger (incorporated by reference to Exhibit 10(17) to our Annual Report on Form 10-K for the fiscal year ended June 30, 1998 (Commission file number 1-4389)).*
10.31	Letter dated August 21, 2003, from Applera to Dennis L. Winger regarding the Letter Agreement dated June 24, 1997, between Applera and Dennis L. Winger (incorporated by reference to Exhibit 10.33 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2003 (Commission file number 1-4389)).*
10.32	Employment Agreement dated as of December 1, 2000, between Applera and Kathy P. Ordoñez (incorporated by reference to Exhibit 10.35 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2002 (Commission file number 1-4389)).*
10.33	Celera Diagnostics Joint Venture Agreement dated as of April 1, 2001, among Applera, its Applied Biosystems Group, its Celera Genomics Group, Foster City Holdings, LLC, and Rockville Holdings, LLC (incorporated by reference to Exhibit 10.36 to our Annual Report on Form 10-K for the fiscal year ended June 30, 2002 (Commission file number 1-4389)).
10.34	Amendment, dated as of June 22, 2004, to Celera Diagnostics Joint Venture Agreement dated as of April 1, 2001, among Applera, its Applied Biosystems Group, its Celera Genomics Group, Foster City Holdings, LLC, and Rockville Holdings, LLC.
10.35	Celera Genomics/Applied Biosystems Marketing and Distribution Agreement dated as of February 27, 2003, and effective as of April 1, 2002 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003 (Commission file no. 1-4389)).
10.36	Amended and Restated Celera Genomics/Applied Biosystems Marketing and Distribution Agreement dated as of June 22, 2004.

11	Computation of Net Income (Loss) per Share for the three years ended June 30, 2004 (incorporated by reference to Note 1 to Consolidated Financial Statements of Annual Report to Stockholders for the fiscal year ended June 30, 2004).

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13	Annual Report to Stockholders for the fiscal year ended June 30, 2004 (to the extent incorporated herein by reference).
21	List of Subsidiaries.
23	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management plan or compensatory plan or arrangement

(b) Reports on Form 8-K

During the fourth quarter of our 2004 fiscal year, we filed (i) a Current Report on Form 8-K dated April 5, 2004, to disclose under Item 5 thereof our April 5, 2004, press release regarding our Board of Directors authorization of the repurchase of up to $100 million of Applera-Applied Biosystems stock following the repurchase of $200 million of Applera-Applied Biosystems stock previously authorized by the Board of Directors, (ii) a Current Report on Form 8-K dated April 27, 2004, to disclose under Item 12 thereof our April 27, 2004, press releases setting forth the financial results of Applera and Applied Biosystems and Celera Genomics for the third quarter of our 2004 fiscal year, and (iii) a Current Report on Form 8-K dated June 2, 2004, to disclose under Item 11 thereof information regarding a trading blackout period under Section 306 of the Sarbanes-Oxley Act of 2002 and Rule 104 of the Securities and Exchange Commission s Regulation BTR.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

APPLERA CORPORATION

By /s/ William B. Sawch

William B. Sawch
Senior Vice President and General Counsel

Date: September 9, 2004

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Tony L. White — September 9, 2004

Tony L. White
Chairman of the Board of Directors, President
and Chief Executive Officer
(Principal Executive Officer)

/s/ Dennis L. Winger — September 9, 2004

Dennis L. Winger
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

/s/ Ugo D. DeBlasi — September 9, 2004

Ugo D. DeBlasi
Vice President and Controller
(Principal Accounting Officer)

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/s/ Richard H. Ayers — September 9, 2004

Richard H. Ayers
Director

/s/ Jean-Luc Bélingard — September 9, 2004

Jean-Luc Bélingard
Director

September __, 2004

Robert H. Hayes
Director

September __, 2004

Arnold J. Levine
Director

/s/ William H. Longfield — September 9, 2004

William H. Longfield
Director

/s/ Theodore E. Martin — September 9, 2004

Theodore E. Martin
Director

/s/ Carolyn W. Slayman — September 9, 2004

Carolyn W. Slayman
Director

/s/ Orin R. Smith — September 9, 2004

Orin R. Smith
Director

/s/ James R. Tobin — September 9, 2004

James R. Tobin
Director

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ON FINANCIAL STATEMENT SCHEDULE

To the Stockholders and Board of
Directors of Applera Corporation

Our audits of the consolidated financial statements referred to in our report dated July 28, 2004, appearing in the 2004 Annual Report to Stockholders of Applera Corporation (which report and consolidated financial statements are incorporated by reference in this Annual Report on Form 10-K) also included an audit of the financial statement schedule listed in Item 15(a)(2) of this Form 10-K. In our opinion, this financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP
PricewaterhouseCoopers LLP

Stamford, Connecticut
July 28, 2004

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APPLERA CORPORATION
VALUATION AND QUALIFYING ACCOUNTS AND RESERVES
FOR THE FISCAL YEARS ENDED JUNE 30, 2002, 2003, and 2004

	ALLOWANCE FOR DOUBTFUL ACCOUNTS
	(Amounts in thousands)
Balance at June 30, 2001	$ 5,070
Charged to income in fiscal year 2002	8,858
Deductions from reserve in fiscal year 2002	(2,978)
Balance at June 30, 2002	10,950
Charged to income in fiscal year 2003	4,288
Deductions from reserve in fiscal year 2003	(4,731)
Balance at June 30, 2003 (1)	10,507
Charged to income in fiscal year 2004	2,866
Deductions from reserve in fiscal year 2004	(4,425)
Balance at June 30, 2004 (1)	$ 8,948

(1) Deducted in the Consolidated Statements of Financial Position from accounts receivable.

SCHEDULE II

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EXHIBIT INDEX

Exhibit Number	
10.10	The Excess Benefit Plan of Applera Corporation, as amended and restated effective July 1, 2004.
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