

Millennium Pharmaceuticals, Inc. > Annual Report 2000



Millennium 2000 > Accelerating downstream >





## To Our Shareholders, Employees and Friends

This year marks an important personal milestone — my twentieth year in biotechnology — and the industry has never been more exciting. As a group, we now have important new ways to identify the causes and map the pathways of human disease. And we have the chance to make a difference in science, medicine and the pharmaceutical industry. Most important, for the first time, we have a *real* opportunity to make a significant difference in the quality of patients' lives.



Millennium is now poised to take the industry to a new level. We have what we believe is the strongest early-stage pipeline in biotechnology, with great breadth across the major diseases. We are focused on three key franchise areas — oncology, metabolic disease and inflammatory disease — in which we have small molecule drugs, biotherapeutic and predictive medicine programs. Above all, we are working to integrate information and technology all the way from gene to patient (G2P).

Yet, there is still work to be done to build the biopharmaceutical company of the future. This report describes the steps we are taking to succeed.

### Developing Breakthrough Products

Millennium views breakthrough products as highly specific therapeutics and predictive medicines that enable us to deliver the right drug to the right patient. Today, we are working to make personalized medicine a reality, developing therapies addressed to the underlying molecular basis of disease — not just the symptoms. For instance, the Melastatin<sup>®</sup> Diagnomic<sup>®</sup> test, based on our discoveries, will provide physicians with molecular-based information about the condition of a melanoma patient, thus guiding treatment decisions. We are also defining pharmacogenomic tests that someday will enable physicians to select the most efficacious and safest drug for each individual. We believe that, in the future, physicians will be able to use these tools to truly customize treatments — identifying not just the disease, but its genetic basis, selecting not just a drug, but the most effective one for the particular patient. We believe these products will change the practice of medicine.



We are able to create such advances because of the scale of our discovery effort and G2P platform — one of the largest in the industry. It has produced an enormous product pipeline with significant retained value in each of our three franchise areas. The result: two product candidates at or near market, six product candidates in the clinic and dozens of potential products in preclinical development.

### Key Franchise: Oncology

Consider a disease that affects eight million people — more than 85% of whom remain underserved.

The disease is cancer, and Millennium is working to change that unacceptable statistic through a broad oncology program aimed at precisely targeting tumor types with both predictive and therapeutic medicines. Indeed, we have two product candidates at or near market and two more in clinical trials. One therapeutic candidate, the CAMPATH® monoclonal antibody developed in partnership with ILEX Products and Schering AG/Berlex, is initially being developed for refractory chronic lymphocytic leukemia (CLL); there are 10,000-12,000 patients in the US and Europe with this advanced form of the disease. Recently, we received a positive recommendation from the Oncologic Drugs Advisory Committee (ODAC) to the US Food and Drug Administration (FDA) for its accelerated approval. We anticipate US approval in early 2001, followed by European approval later in 2001.

Melanoma is an aggressive — and prevalent — cancer; it is responsible for about 79% of skin cancer deaths. We have developed Melastatin®, a Diagnomic® test for malignant melanoma, in collaboration with BD (Becton Dickinson). Significantly similar clinical markers are currently in use in select academic centers allowing physicians in these centers to accurately assess which patients are most at risk of having a melanoma metastasize and which are most likely to remain disease free; these physicians are thus more likely to deliver the right therapy to the right patient.

Our streamlined target-by-class program, conducted in partnership with Bayer AG, has moved a drug candidate from gene discovery to clinical candidate status in less than 18 months, and Bayer is moving aggressively toward Phase I clinical trials.

For Millennium Pharmaceuticals, 2000 was a year of groundbreaking scientific, technological, clinical and innovative business successes. We are now ranked among the world's top biopharmaceutical companies. Most important, we are now poised to realize our vision: to transcend the limits of medicine<sup>SM</sup>.

In 2000, we surged ahead in every area of our organization:

### Breakthrough Products

- ⊙ Accelerated our first products to the threshold of commercialization; we received an ODAC recommendation for accelerated approval of the CAMPATH® monoclonal antibody; and, based on our discoveries, a strategic alliance collaborator readied the Melastatin® test for commercial availability.
- ⊙ Continued to advance our six clinical product candidates, including LDP-341 and LDP-02.
- ⊙ Continued to develop one of the deepest early-stage product pipelines in the industry, with hundreds of targets diversified across multiple disease modalities.

### Productivity

- ⊙ Concluded the second year of our groundbreaking five-year Bayer alliance by identifying more than 80 disease-relevant qualified drug targets for assay configuration.
- ⊙ Increased the productivity of our target discovery process by up to 130%.


### Value Creation

- ⊙ Entered into a novel 50/50 alliance with Aventis Pharmaceuticals for discovery through commercialization valued at up to \$450 million, resulting in one of the largest inflammation pipelines in the industry.

### Organization

- ⊙ Shifted our business focus downstream through late-stage pipeline expansion, structuring new over-the-top alliances and continually revamping our organization to meet our changing needs.

Each of these achievements helps us create value for our shareholders. Each moves us further downstream toward commercialization. Each is critical to building the biopharmaceutical company of the future. Together, they will enable us to transcend the limits of medicine.



In addition, we have initiated Phase II clinical trials for LDP-341, potentially a potent and selective inducer of apoptosis (cell death) in cancer cells through a unique mechanism known as proteasome inhibition. Trials will target a broad range of hematologic malignancies and solid tumors, testing LDP-341 both as a single agent and in combination with other chemotherapeutic agents.

Yet, our oncology efforts go far beyond these four product candidates. By harnessing new technologies we are identifying key antibodies related to cancer of the lung, colon, prostate, breast and ovary. We are working with our partner Bristol-Myers Squibb to find new indications for existing drugs, such as TAXOL®. We are also developing pharmacogenomics programs that we expect will enrich the responder populations of our clinical trials. It is our belief that ultimately these efforts will enable us to treat cancer at its source — and deliver truly personalized medicines to cancer patients.

#### **Key Franchise: Metabolic Disease**

Eighty-eight million people worldwide are obese; twenty-six million have Type II diabetes. Yet, current treatments aid only 10-12% of the total patient population. We believe we can change this by developing novel drugs that are effective for a large number of patients.

Thus, our world-renowned metabolic research and discovery team is seeking ways to treat both the causes and accompanying related conditions of these key metabolic diseases. In each instance, the research is multifaceted. For example, in obesity we are examining pathways from energy use to hunger/satiety signaling to fat absorption. Our discoveries offer the potential for far-reaching impact; imagine the implications to an obese patient of being able to block FATP4, the transporter responsible for the absorption of fatty acids. FATP4 is one of three metabolic programs in late-lead optimization/preclinical development; nine more programs are in early-lead selection.

Additionally, in the first quarter of 2001, we entered into a key strategic alliance with Abbott Laboratories, through which we will jointly seek to develop and commercialize therapeutics for the treatment of metabolic diseases, including obesity and diabetes — and accelerate our downstream progress.

#### **Key Franchise: Inflammatory Disease**


Our third key franchise area is inflammatory disease. We are taking a broad approach, targeting respiratory diseases, multiple sclerosis, rheumatoid arthritis and inflammatory bowel disease. Each of these disease areas represents a large patient population: There are, for example, over 200 million respiratory disease patients worldwide. Significantly, each represents an area in which Millennium products can have a profound effect on patients' lives.

We are making tremendous progress. To date, we have several inflammation-based product candidates in clinical trials, including LDP-977, a targeted therapy for chronic asthma, and LDP-02, a targeted therapy for Crohn's disease and ulcerative colitis. We are also investigating the efficacy of the CAMPATH® monoclonal antibody in multiple sclerosis. In addition, we have two product candidates in Phase I clinical trials: LDP-01 and LDP-519 for stroke. And we have over a dozen product candidates in late-lead selection/preclinical development, including CCR1, a chemokine receptor targeting rheumatoid arthritis, with many more in early-lead selection plus dozens of validated targets.

We are also advancing this franchise through major alliances directed toward both therapeutic and Diagnostics® products; notable among these is our comprehensive alliance with Aventis Pharmaceuticals. These alliances are structured to enable Millennium to participate from discovery through commercialization of the resultant drug candidates, further fueling our pipeline as we continue to move ahead.

#### **Enhancing Productivity across the G2P Platform**

There is currently an unsustainable gap in the pharmaceutical industry between the time and cost of bringing drugs to market and the return those drugs generate.





Millennium has tackled this problem, vowing to increase productivity of the discovery and development process by 100%.

Today, our productivity initiative is continuously enhancing our competitive strength and delivering results for both our partners and ourselves. For example, we established a goal of increasing the efficiency of target discovery activities and processes; in 2000, significant productivity improvements in transcriptional profiling and molecular pathology generated a greater than 130% productivity improvement in delivering qualified targets in our collaboration with Bayer.

Yet, Millennium's future efforts must realize a significant increase in productivity downstream.

One of the major impediments to the productivity of drug discovery and development today is that the ADMET (Absorption, Distribution, Metabolism, Excretion and Toxicology) characteristics of

drug candidates, which have a tremendous effect on safety and efficacy, are frequently not adequately assessed until late-stage clinical trials. However, we are developing predictive ADMET technologies that can be applied earlier in the development process, thus potentially increasing the probability of success for products that move to clinical trials, enabling Millennium to speed products from lead to market — and dramatically magnifying our return on investment in drug development.

#### Creating Value Through Over-the-Top Alliances

Since our founding, Millennium has pursued dual, complementary paths to create shareholder value. We continue to hone our unparalleled science and technology platform, then leverage it to form unprecedented, over-the-top alliances within the biopharmaceutical industry — alliances that, in turn, further our scientific efforts.

As we shift our focus downstream — and establish greater independent market presence — the scope of these alliances is also shifting. We now specifically seek collaborators that can enhance our late-stage pipeline and commercialization opportunities, providing significant downstream momentum. We are also able to structure agreements to leverage the resources of our collaborators, thus greatly increasing our capacity with minimal investment.

Our recent alliances with Aventis Pharmaceuticals and Abbott Laboratories are clear examples of the benefits of such a strategy. Millennium's five-year agreement with Abbott Laboratories will unite the two firms in their work to identify and validate molecular targets

“We are focusing our efforts on rapidly moving downstream toward commercialization — so we can truly affect the quality of patients' lives.”

that play a role in the initiation and progression of metabolic diseases and then utilize this information to jointly develop and commercialize a full spectrum of therapeutic, pharmacogenomic and Diagnostomic® products on a global basis. With Aventis, we seek to jointly develop and commercialize anti-inflammatory drugs, an arrangement that immediately magnifies Millennium's inflammation program, making the joint program one of the largest in the industry. We will also share development efforts and costs for predictive ADMET technologies, which will provide Millennium with the tools to improve drug development productivity, while minimizing the expense of such a program. Each of these alliances also include a major technology transfer effort and an equity investment in Millennium.

Our marketing and development partnership with Taisho Pharmaceutical Company, a large Japanese firm, calls for shared global marketing of LPD-977, furthering our aggressive movement downstream in inflammation.

Similarly, a recent alliance with Roche Diagnostics in the area of rheumatoid arthritis diagnostics will focus on creating novel Diagnostomic® products for personalized medicine.

Of course, we are also focused on expanding our internal resources; for instance, we acquired Cambridge Discovery Chemistry (CDC), a British firm, which gives Millennium a European presence and more than doubles our team of medicinal chemists to accelerate downstream drug discovery efforts.

### Shifting Organizational Focus Downstream

At Millennium, our *modus operandi* is very straightforward: We think aggressively about where we want to be in five to ten years, then put in place the framework required to succeed. This approach applies equally to scientific advancement and to organizational structure. We

have been successful because we have a team of committed people who are dedicated to changing the industry.

Thus, as we now focus on downstream development, we continue to bolster our organization, adding senior management that brings expertise to our manufacturing and commercialization enterprises. Over the last year, we gained capabilities in the drug development, preclinical, clinical and manufacturing areas. More recently, we strengthened our quality assurance and advanced commercialization operations, including

sales and marketing. These positions will help Millennium prepare the market for our product launches, establishing corporate visibility and creating market anticipation.

### Executing the Vision

Millennium has always been known as a company that can envision a great future. We are translating that vision into action.

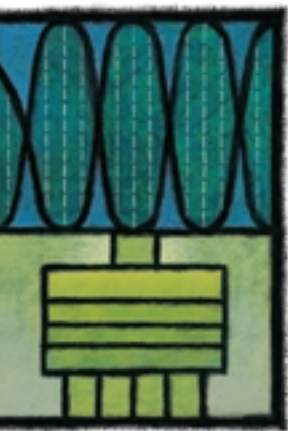
Today, powerful external forces are driving changes in the healthcare system — from consumer power to healthcare policy to the pervasive influence of the Internet. Yet, we believe these forces create new opportunities — to build a company, to change the practice of medicine, to create significant shareholder value.

Eight years ago, Millennium was founded with a vision: to transcend the limits of medicine. We believed we could do that by building a new type of company, the biopharmaceutical company of the future. Now, we are realizing that dream. We are dramatically increasing productivity throughout our G2P platform. We are developing personalized medicine products. And we are focusing our efforts on rapidly moving downstream toward commercialization — so we can truly affect the quality of patients' lives.

This letter would not be complete without thanks from the entire Millennium team for the support of our shareholders as we seek to execute the most ambitious vision that now exists in the pharmaceutical industry. We very much look forward to reporting on even greater successes in 2001.



Mark Levin  
Chairman, President and Chief Executive Officer



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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended: **December 31, 2000**

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: **0-28494**

**MILLENNIUM PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation or organization)

**75 Sidney Street, Cambridge,  
Massachusetts**

(Address of principal executive offices)

**04-3177038**

(IRS Employer Identification No.)

**02139**

(zip code)

Registrant's telephone number, including area code: **(617) 679-7000**

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

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, \$0.001 par value**  
(Title of class)

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

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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant was \$7,101,754,245 based on the last reported sale price of the Common Stock on the Nasdaq Stock Market on February 28, 2001.

Number of shares outstanding of the registrant's class of Common Stock as of February 28, 2001: 215,652,754.

**Documents incorporated by reference:**

Portions of the definitive Proxy Statement for the 2001  
Annual Meeting of Stockholders

Part III

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## PART I

### Item 1. BUSINESS

#### Overview

Our goal is to become the biopharmaceutical company of the future. We plan to develop breakthrough drugs and predictive medicine products that ultimately enable physicians to more closely customize medical treatment by combining knowledge of the genetic basis for disease and the genetic characteristics of a particular patient. We plan to achieve this goal of delivering personalized medicine to patients by building on our broad scientific and technological capabilities and methods, which we call our “technology platform.” We use many of the elements of our technology platform throughout our business, from the discovery of disease-related genes, to the development of drugs to specifically address these diseases, to the development of predictive medicine products and services to enable clinicians and pharmaceutical researchers to make better informed decisions about drug treatment for patients affected by these diseases. As a result, we speak of our technological approach as being applicable from “gene to patient.”

We have entered into research, development and commercialization arrangements with major pharmaceutical and biotechnology companies relating to a broad range of therapeutic and predictive medicine products and services. These alliances provide us with the opportunity to receive royalties and/or share profits if our collaborations are successful in developing and commercializing products. In many cases, we also retain product rights for ourselves from these alliances. We have also entered into technology development and technology transfer arrangements with major pharmaceutical and biotechnology companies. Under each of these arrangements we work cooperatively with the other party to enhance our technology platform or provide such party a license to use our technology platform in exchange for fees and, in some cases, the opportunity to receive royalties if the other party is successful in developing and commercializing products using our technology platform.

References in this Annual Report on Form 10-K to we, us, our, and the like include, where applicable, references to our Millennium Predictive Medicine division, or MPMx, and its predecessor entity, Millennium Predictive Medicine, Inc., which was a wholly-owned subsidiary of ours before it was merged with and into Millennium Pharmaceuticals, Inc. in January 2001.

In this Annual Report on Form 10-K, we incorporate by reference certain information from parts of other documents filed with the Securities and Exchange Commission. The SEC allows us to disclose important information by referring to it in that manner. Please refer to such information.

We were incorporated in Delaware in 1993 and our principal executive offices are located at 75 Sidney Street, Cambridge, Massachusetts 02139.

#### Key Transactions and Developments in 2000 and 2001

##### *Strategic Alliances*

*Aventis.* In June 2000, we formed an alliance with Aventis Pharmaceuticals Inc., the pharmaceutical subsidiary of Aventis S.A., by signing agreements covering:

- joint development and commercialization of drugs for the treatment of specified inflammatory diseases;
- a five-year program for the joint development of new drug discovery technologies;
- the grant to Aventis of rights to our drug discovery technologies in exchange for payments of up to \$200 million over a five-year period; and
- an investment by Aventis of \$250 million in our common stock, of which:
  - Aventis made an investment on July 27, 2000 of \$150.0 million to purchase 2,516,356 shares of our common stock,
  - Aventis made an investment on January 4, 2001 of \$50.0 million to purchase 753,522 shares of our common stock, and

- Aventis has agreed to make a final investment of \$50.0 million later in 2001.

*Abbott.* In March 2001, we formed an alliance with Abbott Laboratories by signing agreements covering:

- joint development and commercialization of drugs and predictive medicine products for the treatment and management of specified metabolic diseases;
- an exchange of rights to certain components of each party's drug discovery technologies and a program for the development of a new drug discovery technology; and
- an investment by Abbott of \$250 million in our common stock, of which:
  - Abbott has agreed to make an initial investment of \$50.0 million in April 2001, and
  - Abbott has agreed to make additional investments totalling \$200 million in seven quarterly installments from later in 2001 through 2003.

#### ***Reacquisition of Minority Interest in MPMx and Restructuring of MPMx***

On June 2, 2000, we reacquired the outstanding minority equity interest in Millennium Predictive Medicine, Inc., through a merger of MPMx into a newly-organized, wholly-owned subsidiary of Millennium. In the merger, we issued an aggregate of approximately 2,240,760 shares of our common stock to the former MPMx shareholders, including Becton Dickinson and Company. In addition, we assumed MPMx's outstanding employee stock options, which are exercisable for 444,214 shares of our common stock. As a result of the merger, we were able to align more closely our therapeutic and predictive medicine discovery and development efforts.

We recently restructured MPMx, and we now operate MPMx as an unincorporated division of our business.

#### ***Acquisition of Cambridge Discovery Chemistry***

On July 27, 2000, we acquired Cambridge Discovery Chemistry Ltd., a subsidiary of Oxford Molecular Group, plc, by purchasing all of the issued and outstanding share capital of CDC for \$50.0 million in cash. We renamed CDC "Millennium Pharmaceuticals Limited." Through this acquisition we added approximately 85 expert chemists, many with significant pharmaceutical chemistry experience, to our drug discovery team, bringing our total chemistry capability to over 150 scientists at completion of the acquisition. By substantially increasing our capabilities in medicinal and computational chemistry, we expect this acquisition to accelerate our downstream drug discovery efforts. We believe that it also establishes a presence for us in one of the strongest and most innovative pharmaceutical and technology centers in Europe.

#### ***Convertible Note Offering***

On January 14, 2000, we completed a Rule 144A offering to qualified institutional buyers of \$400 million of 5.5% Convertible Subordinated Notes due January 15, 2007. The notes are convertible into our common stock at a price equal to \$42.07 per share. We can redeem the notes at any time after January 15, 2003. The holders of the notes can, under specified circumstances, require us to repurchase the notes if a change of control occurs. During 2000, we paid an aggregate of \$54.9 million to induce the early conversion by holders of \$304.1 million of notes. As a result, on December 31, 2000, \$95.9 million of these notes remained outstanding.

#### ***Common Stock Offering***

On October 11, 2000, we completed a public offering of 11,000,000 shares of our common stock at a purchase price of \$64.00 per share. On October 17, 2000, we sold an additional 1,465,500 shares of our common stock pursuant to the underwriters' exercise of their over-allotment option. We realized

net proceeds of \$767.4 million from the offering, after deducting the underwriting discount and our offering-related expenses.

### **Industry Background**

The discovery and development of new drugs typically involves several steps and many years of work. The first step is the identification of a drug “target” for therapeutic intervention—a molecule or structure somewhere in the body, inside or on the surface of cells, which is either directly related to the disease or lies in a biochemical pathway involved in the disease. The next step is to identify compounds which interact with this drug target and modulate the drug target’s activity in a manner that might help reverse, inhibit or prevent the disease process. This step is normally accomplished by screening large collections, referred to as libraries, of synthetic chemicals and natural products in a trial-and-error process designed to identify those compounds that can interact with the drug target.

The most promising compounds to emerge from this time-consuming process are advanced to the next stage, in which synthetic derivatives of these compounds are generated and tested to arrive at one or a few so-called lead compounds. Positive interactions of these lead compounds with the drug target and the subsequent activity in animal or cellular models of the disease may suggest that these compounds can be developed successfully into new drugs. The best of these lead compounds are then subjected to rigorous testing, first in animals and then in humans, to establish their safety and efficacy as drugs.

The selection of new targets for drug discovery historically has been an inefficient process because of the lack of knowledge of the underlying disease causes. Drug targets have often been selected based on speculation that they might be involved in disease processes, rather than because of any clear, well-documented association with specific diseases. As a result, many drug candidates fail during clinical trials because they turn out to be ineffective or unsafe. Moreover, many drugs that do reach the market treat only the symptoms of diseases rather than their underlying causes.

In recent years, however, the drug discovery process has changed, beginning with the process for discovering drug targets. Fueled by a broad interest in determining the entire DNA sequence of the human genome, scientists have made major improvements in the technologies available for identifying and cataloguing genes in complex organisms. These technologies include high-throughput methods for sequencing genes, for monitoring and comparing the expression of genes in different situations and for following the inheritance of genes in families prone to particular diseases. The integration of molecular biology with robotics, information technology and analytical instrumentation is crucial to these technologies. The combination of these disciplines provides powerful capabilities for generating, capturing and analyzing large volumes of data concerning genes and their expression, making it possible for the first time to mount a systematic search to discover and characterize the genes and biochemical pathways which underlie human diseases.

Major advances have also recently been made in the technologies available for screening synthetic chemical and natural-product libraries to identify compounds active against specific drug targets and for the subsequent generation of lead compounds optimized for their activity against these drug targets. As with the advances in target discovery, the advances in drug discovery depend heavily on robotics, information technology and analytical instrumentation, coupled with novel combinatorial approaches to the synthesis of chemical libraries.

Another important recent development in biotechnology has been the emergence of monoclonal antibody-based drugs as successful therapeutics. Monoclonal antibodies, which are specially produced proteins that play a role in the immune system, have long held great potential as drugs because, by their nature, they recognize and interact with target molecules in a highly specific way. However, early therapeutic monoclonal antibodies were generated in non-human animals and, therefore, were recognized by the body as foreign and neutralized by the immune system. Recently, it has become possible to produce humanized monoclonal antibodies that appear less foreign to the body, and even to

produce completely human monoclonal antibodies in quantity. As a result, monoclonal antibodies are now realizing their potential as drugs, with several successfully on the market, and many more in advanced clinical development.

We believe that the combined effect of these developments has reduced and will continue to reduce the risk, time and expense associated with the development of new drugs. These developments have created an opportunity for biopharmaceutical companies with cutting edge technologies to deliver new classes of drugs which are safe and effective for treating a broad range of important diseases in diverse individuals.

## **Our Strategy**

We combine a variety of proprietary and non-proprietary technologies and know-how to systematically study genes in the context of disease and to discover and develop proprietary therapeutic and diagnostic human healthcare products and services. We believe that our platform is unique in the breadth and diversity of the technologies that it encompasses, and the degree to which we have integrated these technologies. We use advanced capabilities in information technology, robotics, genetics, genomics, molecular biology, cell biology, immunology, biochemistry, chemistry, microfluidics and analytical instrumentation. By combining these capabilities, we have created a series of high-throughput processes that we believe have the potential to improve the efficiency of the discovery and development of therapeutic and diagnostic products, as well as the quality of these products. We believe that these products will change the practice of medicine.

Our business is built around three principal areas of focus:

*Technology.* We use many technologies in each step of the therapeutic and diagnostic product discovery and development processes. We seek the most advanced methods available to integrate into our technology platform, whether developed internally or licensed from third parties, in order to increase the efficiency and productivity of these processes. We believe that our platform will enable us to:

- identify commercially important genes;
- elucidate their functions;
- validate targets for product development;
- identify and develop drug and diagnostic candidates for clinical development; and
- bring novel personalized medicines to the market.

*Therapeutics.* We have three fields of major emphasis: cancer, metabolic diseases, including obesity, and inflammation. We also have significant programs in infectious diseases, cardiovascular diseases and diseases of the central nervous system. We seek to discover disease-related genes, produce validated drug targets and drug leads, and develop and commercialize new, proprietary drugs to treat major human illnesses. We direct these efforts at both small-molecule drugs, which are typically formulated into pills for oral consumption, as well as monoclonal antibodies and proteins, which are typically only available in injectable form.

*Predictive Medicine.* We seek to develop products and services that will provide clinicians and pharmaceutical researchers with information that enables them to make better informed decisions about drug treatment and other aspects of patient management. Our core areas of focus include Diagnostomics® products and pharmacogenomics. A Diagnostomics® product is a gene-based diagnostic test to determine the patient's medical status and facilitate cost-effective treatment. Pharmacogenomics is the identification of genes, or their activity, associated with responsiveness to particular drugs. We believe that predictive medicine products and services will enable physicians to customize medical treatment by providing them with the ability to identify the genetic basis for a patient's disease and select the most appropriate drugs and treatment regimen for the particular patient.

The key initiatives to implement our strategy are:

*Establish and expand strategic alliances.* Based on the strength of our technology platform and product development pipeline, we have established a series of strategic alliances with major pharmaceutical and biotechnology companies. These alliances provide us with substantial revenues and other financing, furnish us with access to important technology, broaden our product development pipeline and reduce our product development risks. These alliances also enhance our ability to bring products to market because of our collaborators' substantial resources and expertise in research, preclinical and clinical development, regulatory issues, manufacturing and marketing.


*Expand downstream pipeline and other skills through acquisitions.* We continually consider joint development, merger and other acquisition opportunities that may provide us with access to products currently on the market or which are in later stages of commercial development or may bring us scientific or other skills that enhance our existing capabilities. For example, through our merger with LeukoSite, Inc. in December 1999, we obtained six drug candidates in clinical development and more than 12 preclinical development programs. In addition, as a result of the LeukoSite merger, we augmented our capabilities in the areas of immunology, preclinical and clinical development and regulatory affairs. Our acquisition of Cambridge Discovery Chemistry Ltd. in July 2000 added approximately 85 expert chemists, many with significant pharmaceutical chemistry experience, to our drug discovery team, substantially increasing our capabilities in medicinal and computational chemistry. We believe that integrating these acquired capabilities with our other resources will facilitate bringing our internally developed products to market quickly and efficiently.

*Enhance proprietary technology platform.* We are committed to continually enhancing our technology platform by incorporating the latest technological advances. Our technology enhancement activities are based on our own internal development efforts and our program to identify, evaluate and integrate technologies licensed from third parties. The quality of our technology platform has been central to our ability to attract a broad range of strategic alliances with major pharmaceutical and biotechnology companies. Our platform also has enabled us to create a technology transfer alliance in the area of agriculture with Monsanto Company, and a broad technology transfer alliance with Aventis.

## Our Technology

Our comprehensive and industrialized technology platform is based on multiple, parallel approaches to high-throughput product discovery and development which are integrated through the latest advances in enabling technologies and informatics. The enabling technologies include robotics, fluidics, miniaturization and analytical instrumentation. Informatics consists of the tracking, synthesizing and interpretation of the enormous volumes of data generated in high-throughput discovery of genes, drug targets and drugs.

The following chart illustrates how we apply various processes of our technology platform to the principal steps in the discovery and development of drugs, spanning from gene to patient.

		PROCESSES															
		Genetics	DNA Sequencing	Expression cloning	Transcriptional profiling	Molecular pathology	Functional genomics	Proteomics	Computational biology	Bench biology	Pathway profiling	Pharmacogenomics	Chemistry	Computational chemistry	Predictive pharmacology	Clinical research	Regulatory affairs
<b>GENE</b>  <b>PATIENT</b>	STAGE																
	Gene identification	●	●	●	●		●	●	●	●	●						
	Target identification	●		●	●	●	●	●	●	●	●						
	Target validation	●		●	●	●	●	●	●	●	●					●	
	Lead identification and optimization				●	●			●	●			●	●	●		
	Preclinical candidate identification and validation				●	●		●		●	●	●	●	●	●		●
	Clinical trials	●			●	●		●				●			●	●	●
Patient management	●			●	●						●					●	

- **Human, mouse and microbial genetics** involve the identification of genes associated with diseases or with the ability of microbes to survive.
- **High-throughput sequencing** enables the rapid determination of DNA sequence information from large numbers of genes.
- **Expression cloning** means the isolation and identification of genes according to the biological properties of the proteins they encode.
- **Transcriptional profiling** is the rapid identification of genes whose activity in the body changes under disease conditions.

- **Functional genomics** are the assignment of biochemical functions and disease roles to gene products and the selection of the relatively small number of gene products that will be appropriate targets for therapeutic intervention.
- **Proteomics** constitutes the identification of proteins, or changes to proteins, associated with particular diseases.
- **Computational biology** is the rapid analysis of the DNA sequences of genes to identify those which encode potential targets for drugs.
- **Bench biology**, using cellular and animal models, is utilized for the experimental confirmation of hypotheses that particular genes or proteins could be good targets for drugs.
- **Pathway profiling** identifies multiple genes that may be involved in the initiation, progression or maintenance of a disease.
- **Pharmacogenomics** constitutes the identification of genes, or their activity, associated with responsiveness to particular drugs.
- **Chemistry** is utilized for the identification and optimization of small-molecule compounds active against particular drug targets.
- **Computational chemistry** is employed to enable the modeling and analysis of chemical structures and their interactions with drug targets.
- **Predictive pharmacology** enables the prediction of likely behaviors of drug candidates when they are administered to humans.
- **Clinical research** is conducted to assess the safety and efficacy of drugs in humans.
- **Regulatory affairs** is the process of gaining necessary approvals from the appropriate governmental agencies that regulate the testing and marketing of drugs.

## Therapeutics—Clinical Programs

We have six drug candidates in clinical development. The following chart identifies each of these clinical drug candidates, and the respective disease indication, our partners or collaborators for these clinical programs and the current phase of the clinical programs.

<u>Product</u>	<u>Disease Indication</u>	<u>Partner/Collaborator</u>	<u>Clinical Phase</u>
CAMPATH® (alemtuzumab) monoclonal antibody	Cancer (Chronic lymphocytic leukemia)	50/50 partnership between Millennium and ILEX Products, Inc.; distribution agreement with Schering AG/Berlex Laboratories	Biologics License Application submitted December 1999; on December 14, 2000, the Oncologic Drugs Advisory Committee to the FDA recommended accelerated approval for patients with chronic lymphocytic leukemia who have been unsuccessfully treated with alkylating agents and have not responded to therapy with the drug fludarabine; on February 20, 2001, the FDA issued a Class I complete response letter
CAMPATH® (alemtuzumab) monoclonal antibody	Multiple sclerosis	Same as above	Phase II
CAMPATH® (alemtuzumab) monoclonal antibody	Transplantation	Same as above	Phase II
LDP-02	Inflammatory bowel disease	Genentech	Phase IIb
LDP-977	Asthma	Marketing agreement with Taisho in Asia and Europe	Phase IIa
LDP-01	Stroke	none	Phase IIa
LDP-341	Cancer	none	Phase II
LDP-519	Stroke	none	Phase I

Human clinical trials typically are conducted in three sequential phases, although phases may overlap. Phase I trials consist of testing the product in a small number of patients or healthy volunteers, primarily for safety, in one or more dosages, as well as characterization of a drug's pharmacokinetic or pharmacodynamic profile. In Phase II, in addition to safety, the efficacy of the product is evaluated. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded population.



## **Therapeutics—Research and Development Programs**

Using our advanced technology platform, we seek to discover and develop proprietary therapeutic and diagnostic human healthcare products and services to detect, treat and manage a broad array of illnesses. We have three fields of major emphasis: cancer; metabolic diseases, including obesity; and inflammation. We also have significant programs in infectious diseases, cardiovascular diseases and diseases of the central nervous system. The following is a summary of our principal research and development programs:

### ***Cancer***

In the field of cancer, or oncology, we are engaged in clinical development of two compounds, and in target and drug discovery, primarily through strategic alliances. Our programs address a variety of cancers, including leukemia, prostate, breast, lung, colorectal, multiple myeloma, non-Hodgkin's lymphoma and melanoma.

The following two cancer product candidates are in clinical trials:

The *CAMPATH*<sup>®</sup> (alemtuzumab) product candidate is a humanized monoclonal antibody being evaluated for the treatment of patients with chronic lymphocytic leukemia, which is the most prevalent form of adult leukemia. The *CAMPATH*<sup>®</sup> monoclonal antibody is being developed by Millennium & ILEX Partners, L.P., our joint venture with ILEX Products, Inc., a subsidiary of ILEX Oncology, Inc. The partnership completed the submission to the U.S. Food and Drug Administration in December 1999 of a biologics license application for the *CAMPATH*<sup>®</sup> product candidate for patients who are not responsive to traditional therapy. The FDA has granted fast track status to its review of this application. On December 14, 2000, the Oncologic Drugs Advisory Committee to the FDA recommended accelerated approval for patients with chronic lymphocytic leukemia who have been unsuccessfully treated with alkylating agents and have not responded to therapy with the drug fludarabine. On February 20, 2001, the FDA issued a Class I complete response letter. In the letter, the FDA indicated that the timeframe for accelerated approval has been extended for a 60-day period. Millennium & ILEX Partners expects to complete ongoing discussions with the FDA on final package labeling and design of a post-marketing confirmatory study for *CAMPATH*<sup>®</sup> during this time. The partnership has entered into a worldwide, other than the Far East, distribution agreement with Schering AG and its affiliate, Berlex Laboratories. The *CAMPATH*<sup>®</sup> monoclonal antibody has received an orphan drug designation from the FDA, which may entitle Millennium & ILEX Partners to a seven-year marketing exclusivity period in the United States for the *CAMPATH*<sup>®</sup> product candidate.

*LDP-341* is a small-molecule drug candidate for the treatment of diverse cancers. *LDP-341* has a unique mechanism of action, inhibition of the proteasome, which is the cellular component responsible for protein degradation. We completed Phase I clinical trials of *LDP-341* for the treatment of multiple myeloma in early 2001. We began a Phase II clinical trial of *LDP-341* for the treatment of multiple myeloma in the first quarter of 2000, and we expect to begin a series of Phase I/II and Phase II clinical trials of *LDP-341* for the treatment of additional oncology indications in solid tumors as well as hematological malignancies as both a single agent and in combination with other chemotherapeutic agents later in 2001.

We have entered into two strategic alliances for target and drug discovery in cancer:

*Lilly.* We have an alliance with Lilly focused on finding small-molecule drug targets in select areas of cancer, including prostate cancer and mechanisms of drug resistance. We received four milestone payments from Lilly during 2000 under this alliance for the delivery of three cancer drug candidate genes and the acceptance of one validated target for cancer drugs.

*Bayer.* Our multi-disease alliance with Bayer includes discovery of small-molecule drug targets for areas of cancer that fall outside of our Lilly collaboration.

### *Metabolic Diseases*

The field of metabolic diseases includes obesity, type 2 diabetes and wasting disorders, such as cancer cachexia. In March 2001, we entered into a broad alliance with Abbott Laboratories that includes joint development and commercialization of drugs for the treatment and management of obesity and type 2 diabetes. Both companies are contributing their research pipelines in these disease areas to the collaboration, which will include more than 35 projects at the outset. Other targets in the field of metabolic diseases that we are pursuing independently of our agreement with Abbott include MC4, a target for the regulation of food intake that we are pursuing for cancer cachexia and other wasting disorders.

### *Inflammation*

Inflammation encompasses a broad spectrum of human diseases and conditions, including rheumatoid arthritis, asthma and chronic obstructive pulmonary disease, multiple sclerosis, inflammatory bowel disease and stroke. In June 2000, we entered into a broad agreement in the field of inflammation with Aventis Pharmaceuticals that includes joint development and commercialization of drugs for the treatment of specified inflammatory diseases. Our agreement with Aventis covers a substantial portion of our research and development program in inflammation.

In the field of inflammation, we have four products in clinical development:

- *LDP-977* is a small-molecule drug candidate for the treatment of asthma. LDP-977 is designed to selectively inhibit the production of leukotrienes, a class of molecules that plays an important role in bronchial asthma. A Phase IIa trial of LDP-977 has been completed and we expect to begin Phase IIb trials in patients with asthma later this year. In January 2000, we entered into an agreement with Taisho Pharmaceutical Company, Ltd. relating to the development, marketing and sale of LDP-977 in Europe and Asia.
- *LDP-519* is a small-molecule drug candidate for the treatment of post-ischemic reperfusion injury, which is inflammatory damage that occurs when blood supply to a tissue is restored after an interruption such as that resulting from organ transplantation, stroke or myocardial infarction. We completed a Phase I clinical trial of LDP-519 in 2000. As with LDP-341, LDP-519 acts through the inhibition of the proteasome.
- *LDP-02* is a humanized monoclonal antibody for the treatment and management of patients with inflammatory bowel disease, including ulcerative colitis and Crohn's disease. We have a collaboration agreement with Genentech, Inc. for the development and commercialization of LDP-02. We are currently enrolling patients for both a Phase II clinical trial of LDP-02 for the treatment of Crohn's disease and a Phase IIb clinical trial for the treatment of ulcerative colitis.
- *LDP-01* is a humanized monoclonal antibody for prevention of post-ischemic reperfusion injury. We completed a Phase IIa clinical trial of LDP-01 in renal transplantation 1999. In 2000 we completed enrollment of a Phase I/II study in patients with stroke.

Outside of our collaboration with Aventis, we are also engaged in two other strategic alliances for target-specific drug discovery and development in the field of inflammation:

*Roche Bioscience.* We have an alliance with Roche Bioscience to develop a small-molecule antagonist of a chemokine receptor known as CCR3 to block the recruitment of inflammatory cells for the treatment of patients with asthma and allergies.

*Kyowa Hakko.* We have a collaboration agreement with Kyowa Hakko for the discovery and development of small-molecule antagonists to chemokine receptors for the treatment of inflammatory and autoimmune diseases.

### ***Infectious Diseases***

*Bacterial Infections.* We are engaged in identifying and validating new targets for antibacterial drugs and in high-throughput screening to identify potential lead compounds. We are conducting these activities in collaboration with American Home Products. During the first four years of this alliance we have delivered twelve antibacterial targets to American Home Products, and have received multiple milestone and bonus payments in return. In January 2001, we identified one pre-clinical antibacterial compound.

*Viral Infections.* Our multi-disease collaboration with Bayer includes the discovery of drug targets that may enable the development of novel small-molecule compounds for the treatment of patients with viral diseases.

### ***Cardiovascular Diseases***

In the field of cardiovascular diseases, we are engaged in the identification and validation of new drug targets. We are conducting this activity in collaboration with Eli Lilly in connection with congestive heart failure and with Bayer in connection with other cardiovascular diseases.

### ***Central Nervous System Diseases***

In the field of central nervous system diseases, we are engaged in the identification and validation of new drug targets for the treatment of affective disorders, schizophrenia, generalized depression, epilepsy and neurodegenerative disorders, such as Alzheimer's disease. We have a strategic alliance with American Home Products in the area of central nervous system diseases. We have delivered seven novel genes to American Home Products under this alliance, receiving milestone payments in return. The area of pain is also included in our multi-disease alliance with Bayer.

## **Predictive Medicine**

An important strategic focus for us is the application of our technology platform to develop products and services that will provide clinicians and pharmaceutical researchers with information that enables them to make better informed decisions about drug treatment and other aspects of patient management. We are conducting this work through our MPMx division.

MPMx is focusing its efforts on diagnostics and pharmacogenomic services and expects to expand into the provision of information services related to patient management.

### ***Diagnomics® Products***

Many current diagnostic tests are directed towards the symptoms, rather than the causes, of the diseases that they are used to diagnose or monitor. As a result, these tests generally provide information only about a patient's current condition. In contrast, we are developing gene-based diagnostic tests, which we call Diagnomics® tests, to assess the underlying causes of diseases. We believe that Diagnomics® products and services will provide information with inherent prognostic, therapeutic and economic implications, facilitating a shift in medical care towards planned and cost-effective treatment of the underlying causes of disease.

We are engaged in two strategic collaborations as part of our Diagnomics® program.

*Becton Dickinson.* In February 1999, we entered into a strategic alliance with Becton Dickinson focused primarily on Diagnomics® products for specified cancers. Under this agreement, we are undertaking research to identify and deliver clinically validated diagnostic markers to Becton Dickinson for skin, cervical, breast, ovarian, uterine and prostate cancers. A diagnostic marker is a molecule or substance whose presence or concentration can be measured in a biological sample taken from a

patient, providing useful information about the patient's status or future prospects with respect to a particular disease or diseases. For example, under license from Millennium, Becton Dickinson is developing the Melastatin® product, a clinical marker to diagnose melanoma. In June 2000, we entered into a licensing agreement with Becton Dickinson in the area of colon cancer diagnostics. Under this agreement, Becton Dickinson paid us a licensing fee in exchange for research and development rights to select diagnostic markers and related intellectual property that we develop in this disease area. We have also granted Becton Dickinson an option to obtain a royalty-bearing, worldwide license from us to commercialize diagnostic markers arising out of the research and development program.

*Roche Diagnostics.* In December 2000, we entered into a collaborative research agreement with Roche Diagnostics, relating to the development of diagnostic products for rheumatoid arthritis. Under the agreement, we have granted Roche research and development rights to select diagnostic markers and related intellectual property developed by us in this disease area. Roche has agreed to pay us a licensing fee, funding for research, milestone payments and royalties. We have granted Roche the right to commercialize, on a worldwide basis, any diagnostic products resulting from the alliance. The research and development program is for a term of three years.

### ***Pharmacogenomics***

Different people often respond in different ways to the same drug. A drug that is safe and effective in one patient may be toxic or ineffective in another. We believe that these differences in response, in part, reflect genetic variations between the individuals concerned. Pharmacogenomic studies seek to establish correlations between specific genetic variations and specific responses to drugs. By establishing such correlations, pharmacogenomics may permit both new and existing drugs to be targeted to those patients in whom they are most likely to be both effective and safe. In November 1999, we entered into a strategic alliance with Bristol-Myers Squibb focused primarily on the application of pharmacogenomics to cancer treatments.

### **Alliances**

A fundamental component of our business strategy is to form alliances with major pharmaceutical and biotechnology companies. In general, our alliances fall into three categories:

- Alliances focused on particular diseases, in which we perform drug discovery research funded by our collaborators. The principal terms of our largest disease-focused alliances, with Bayer, Aventis and Abbott, are as follows:
  - We formed the Bayer alliance in September 1998. This alliance is for a five-year term and covers several disease areas, including cardiovascular disease, cancer, pain, blood diseases and viral infections. Under this alliance, we are eligible to receive up to \$465 million from Bayer. Bayer has already made a \$96.6 million equity investment and paid a portion of the research and development funding. By the end of 2000, we had delivered to Bayer more than 80 disease-relevant qualified drug targets for assay configuration, of which 15 qualified drug targets had moved into high-throughput screening or lead identification. In January 2001, we and Bayer announced our discovery of the first genome-derived small-molecule drug candidate to emerge from our joint research alliance.
  - We formed the Aventis alliance in June 2000. This alliance is for a five-year term and is primarily for collaborative research and development in the area of inflammation. In North America, we have agreed to share the responsibility for and cost of developing, manufacturing and marketing products arising from the alliance. Outside of North America, Aventis is responsible for and will bear the cost of developing, manufacturing and marketing products arising from the alliance, and has a royalty obligation to us. Our arrangement with Aventis also includes an equity investment by Aventis, under which we are eligible to receive up to

\$250 million, and a technology transfer agreement, under which we are eligible to receive up to \$200 million. We have already received a portion of this funding.

- We formed the Abbott alliance in March 2001. This alliance is for a five-year term, and is primarily for collaborative research and development in the area of metabolic diseases. We and Abbott have agreed to share equally the cost of developing, manufacturing and marketing products on a worldwide basis. Our arrangement with Abbott also includes an equity investment by Abbott, under which we are eligible to receive up to \$250 million, and a technology exchange and development agreement.
- Alliances focused on drug discovery for specific targets or the development of a specific product candidate. For example, we have an alliance with Roche Bioscience to develop a small-molecule antagonist of a chemokine receptor known as CCR3 to block the recruitment of inflammatory cells for the treatment of patients with asthma and allergies. One of our key product development alliances is with ILEX Products, Inc., focused on the clinical development of the CAMPATH® monoclonal antibody for the treatment of chronic lymphocytic leukemia.
- Alliances based on the transfer of our technology platform. The principal terms of our largest technology transfer alliances, with Monsanto Company and Aventis, are as follows:
  - We formed a five-year alliance with Monsanto in October 1997. In connection with this collaboration, Monsanto established a wholly-owned subsidiary, Cereon Genomics, based in Cambridge, Massachusetts. We have granted Cereon and Monsanto an exclusive royalty-bearing worldwide license to use our genomics technologies in the fields of plant agriculture and aspects of dairy agriculture. We also granted a non-exclusive worldwide license to Monsanto to apply our genomics technologies outside of these fields. Under this collaboration, we are eligible to receive up to \$218 million, plus royalties. We have already received a substantial portion of this funding.
  - We formed a five-year alliance with Aventis in June 2000. This alliance includes a broad non-exclusive technology transfer arrangement under which we are transferring key elements of our technology platform to Aventis to enhance Aventis's current capabilities. This alliance also includes a technology development component under which we will work collaboratively with Aventis to develop further enhancements to our technology platform. Of the total \$450 million we are eligible to receive under the alliance with Aventis, we are eligible to receive up to \$200 million in funding in connection with the technology transfer arrangement. We have already received a portion of this funding.

Our disease-focused alliance agreements and our target-specific and product-specific alliance agreements generally provide for the funding by our collaborator of some portion of a research program to be conducted by us in conjunction with the collaborator, and the grant of license rights by us to our collaborator to develop and commercialize specified products and services resulting from discoveries made in the research program. In many cases, we have retained development and commercialization rights for ourselves to certain therapeutic and diagnostic applications of discoveries made in the research program. In some cases, if specified research, product development or regulatory milestones are achieved, our collaborators are obligated to make milestone payments to us. In addition, our alliance agreements generally entitle us to royalties or a share of profits on product sales, which are payable for the life of the applicable patents or a specified period of time.

The agreements governing these alliances are subject to various contingencies, including in some cases, early termination rights. We have generally agreed with our collaborators that, for a specified period of time while the alliance is in place, we will not conduct research, independently or with third parties, in the fields covered by the alliance agreement.

Our technology transfer alliance agreements generally provide for the non-exclusive grant of license rights by us to our collaborator to use our technology platform for biotechnology research and development. Typically, our collaborators are obligated to make periodic payments to us and/or to pay us royalties on products they develop using our technology platform.

Our ability to obtain ongoing funding for our sponsored research and technology transfer programs and certain milestone payments under these programs, if any, depends on these alliances continuing for their full term and on our ability to achieve specified research objectives.

Since inception, substantially all of our revenues have been derived from our strategic alliances. For the twelve-month period ended December 31, 2000, revenues from our strategic alliance with Bayer accounted for approximately 27% of our total revenues, revenues from our strategic alliance with Monsanto accounted for approximately 22% of our total revenues, and revenues from our strategic alliance with Aventis accounted for approximately 10% of our total revenues.

The following table sets forth information about our principal current alliances:

Year Established	Collaborator	Alliance Type	Subject
2001	Abbott	Disease-focused, technology exchange and development	Metabolic diseases, technology
2000	Roche Diagnostics	Disease-focused	Rheumatoid arthritis diagnostics
2000	Becton Dickinson	Disease-focused	Colon cancer diagnostics
2000	Aventis	Disease-focused, technology transfer and technology development	Inflammation, technology
2000	Taisho Pharmaceutical	Product development	LDP-977 for asthma
1999	Schering AG/Berlex Laboratories	Product distribution	CAMPATH® monoclonal antibody
1999	Bristol-Myers Squibb	Disease-focused	Cancer pharmacogenomics
1999	Becton Dickinson	Disease-focused	Cancer diagnostics
1998	Bayer	Disease-focused	Cardiovascular diseases, cancer, pain, blood diseases and viral infections
1997	Kyowa Hakko	Target-specific discovery	CCR1 and CXCR3 chemokine receptors
1997	Monsanto	Technology transfer	Agriculture
1997	Genentech	Product development	LDP-02
1996	American Home Products	Disease-focused	Bacterial diseases
1996	ILEX Products, Inc.	Product development	CAMPATH® monoclonal antibody
1996	Roche Bioscience	Target-specific discovery	CCR3 chemokine receptor
1996	American Home Products	Disease-focused and technology transfer	Central nervous system diseases, technology
1996	Eli Lilly	Disease-focused	Cancer
1995	Aventis	Target-specific discovery	NF-κB Inflammation
1995	Eli Lilly	Disease-focused and technology transfer	cardiovascular diseases, technology

### Research and Development

Company-sponsored research and development expenses totaled \$77.0 million in 2000 and \$19.3 million in 1999. Our strategic collaborator-sponsored research and development expenditures totaled \$191.7 million in 2000 and \$140.6 million in 1999. Substantially all of our research and development expenses were sponsored by our strategic collaborators in 1998. In calculating strategic-collaborator sponsored research and development expenditures, we have included expenditures in programs for which we receive current funding as well as programs for which we may receive future compensation as milestone payments, royalties or otherwise even though we provide the current funding. Our research and development expenditures in 2000 increased significantly over 1999 as we added personnel and expanded research and development activities to accommodate existing and added strategic alliances and development efforts, and as a result of the addition, through our acquisition of LeukoSite, Inc., in December 1999, of several preclinical product candidates and six product candidates in clinical trials.

## Patents and Proprietary Rights

We generally seek United States and foreign patent protection for the genes, proteins, antibodies and small-molecule drug leads that we discover, as well as therapeutic, diagnostic and pharmacogenomic products and processes, drug screening methodologies and other inventions based on such genes, proteins, antibodies and small-molecules. We also seek patent protection or rely upon trade secret rights to protect certain other technologies which may be used to discover and characterize genes, proteins, antibodies and small-molecules and which may be used to develop novel therapeutic, diagnostic and pharmacogenomic products and processes. As of December 31, 2000, we and our subsidiaries owned 138 U.S. patents and 10 foreign patents, and more than 1,400 pending U.S. and foreign patent applications. Our issued U.S. and foreign patents expire on various dates between 2012 and 2019.

We own three issued U.S. patents and several pending U.S. and foreign patent applications related to the Melastatin<sup>®</sup> product. We are an exclusive licensee under two issued U.S. patents and pending U.S. and foreign patent applications related to LDP-01. The LDP-01 license extends through the expiration of the licensed patents in 2016. We also own pending U.S. and foreign patent applications related to LDP-02. We also own issued U.S. patents, granted foreign patents and pending U.S. and foreign applications related to LDP-977 and LDP-341. We also are the exclusive licensee of an issued U.S. patent and pending U.S. and foreign applications and we own an issued U.S. patent and pending U.S. and foreign applications related to LDP-519. The LDP-519 license extends through the expiration of the licensed patents in 2015.

We have entered into several license agreements under which we have acquired certain rights to use proprietary technologies and compounds. In particular, we have exclusive and non-exclusive licenses as set forth in an agreement with BTG International Ltd. to make, use and sell products containing the CAMPATH<sup>®</sup> monoclonal antibody. This license extends through the expiration of the licensed patents in 2015. The agreement requires the payment of royalties to BTG. In addition, BTG may terminate the license agreement under certain circumstances, including in the event of a breach of the agreement or if there is a failure to meet commercialization requirements.

In the event our in-licensed rights were terminated or modified, our ability to manufacture and sell products using the covered technologies would be materially adversely affected.

We also currently own the following trademarks and servicemarks: “Changing the Practice of Medicine”<sup>SM</sup>, Chemoprediction<sup>TM</sup>, Cytomed<sup>®</sup>, DGx<sup>®</sup>, Diagnostics<sup>®</sup>, Expression Explorer<sup>®</sup>, G2P<sup>TM</sup>, “Gene to Patient”<sup>TM</sup>, the Millennium “M” logo and design (registered), MBio<sup>TM</sup>, Melastatin<sup>®</sup>, Millennium<sup>®</sup>, Millennium Biotherapeutics<sup>®</sup>, Millennium Information<sup>TM</sup>, Millennium Pharmaceuticals<sup>®</sup>, Millennium Predictive Medicine<sup>®</sup>, MPMx<sup>®</sup>, Pharmacoinformatics<sup>TM</sup>, Protein Explorer<sup>TM</sup>, RADE<sup>TM</sup>, Sequence Explorer<sup>®</sup>, SmartChip<sup>®</sup>, and “Transcending the Limits of Medicine”<sup>SM</sup>. CAMPATH<sup>®</sup> is a registered trademark, and MABCAMPATH<sup>TM</sup> is a trademark, of Millennium & ILEX Partners.

## Government Regulation

### *Overview Of FDA Regulations*

Biological and non-biological drugs, including our products under development, and medical devices, are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local governments. Federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, reporting, labeling, distribution, promotion and marketing of pharmaceutical and diagnostic device products. If these products are marketed abroad, they also are subject to export requirements and to regulation by foreign governments. Failure to comply with applicable regulatory requirements may subject a company to administrative or judicially imposed sanctions, such as warning letters, product recalls, product seizure, injunctions, civil penalties, criminal prosecution, suspension of production, license revocation, or FDA refusal to approve pending marketing applications.



The applicable regulatory clearance process, which must be completed prior to the commercialization of a product, is lengthy and expensive. FDA requirements for our products under development vary depending upon whether the product is a non-biological drug or biological drug. Our monoclonal antibody product candidates currently in human clinical or late preclinical development (*i.e.*, the CAMPATH® monoclonal antibody, LDP-01 and LDP-02) are regulated by the FDA as biological drugs. We believe that products under development in our small-molecule antagonist program will be regulated as non-biological drugs. We are also developing diagnostic products that will be regulated as medical devices.

#### ***Regulation of Non-Biological Drugs and Biological Drugs***

Non-biological drugs and biological drugs are subject to some of the same laws and regulations. Ultimately, however, they are approved under somewhat different regulatory frameworks. Product development and approval within either regulatory framework takes a number of years, involves the expenditure of substantial resources and is uncertain. Many non-biological drugs and biological drugs that initially appear promising ultimately do not reach the market because they are not found to be safe or effective under the standards applied by FDA, or cannot meet the FDA's other regulatory requirements for product manufacture and sale. In addition, the current regulatory framework may change or additional regulations may arise at any stage of our product development that may affect approval, delay the submission or review of an application or require additional expenditures by us.

The activities required before a new non-biological drug or biological drug can be marketed in the United States begin primarily with preclinical testing. Preclinical tests include laboratory evaluation of product chemistry, toxicology and other characteristics. Animal studies are used to assess the potential safety and efficacy of the product as formulated. Many preclinical studies are regulated by the FDA under the current Good Laboratory Practice, or GLP, regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated if the data are to be submitted to the FDA in support of a marketing application.

The entire body of preclinical development work necessary to administer investigational non-biological drugs and biological drugs to human volunteers or patients is summarized in an investigational new drug application, or IND, submitted to the FDA. FDA regulations provide that human clinical trials may begin 30 days following submission of an IND application, unless the FDA advises otherwise or requests additional information, clarification or additional time to review the application. Once trials have commenced, investigators must promptly report all unanticipated risks and adverse events that occur to human subjects to the Institutional Review Board, or IRB, and the drug sponsor during clinical trials. The sponsor must promptly report an adverse event that is unexpected, serious, and possibly drug-related to the FDA. The FDA may stop the trials by placing a "clinical hold" on such trials because of concerns about, for example, the safety of the product being tested. Such holds can cause substantial delay and in some cases may require abandonment of a product.

Clinical testing in humans involves the administration of the investigational non-biological drug or biological drug to healthy volunteers or to patients under the supervision of a qualified principal investigator, usually a physician, pursuant to an FDA reviewed protocol. Each clinical study is conducted under the auspices of an IRB at each academic center, hospital or other research facility at which the study will be conducted. The IRB must approve the protocol and informed consent documents before a clinical trial can proceed. An IRB will consider, among other things, ethical factors, the safety of human subjects, whether informed consent was properly obtained, and the possible liability of the institution.

Human clinical trials typically are conducted in three sequential phases, but the phases may overlap. Phase I clinical trials consist of testing the product in a small number of patients or normal volunteers, primarily for safety, in one or more dosages, as well as characterization of a drug's pharmacokinetic and/or pharmacodynamic profile. In Phase II clinical trials, in addition to safety, the

efficacy of the product is evaluated in a patient population. Phase III clinical trials typically involve additional testing for safety and clinical efficacy in an expanded population at multiple geographically dispersed sites. A clinical plan, or “protocol,” is submitted to the FDA prior to commencement of each clinical trial. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time for a variety of reasons, particularly if safety concerns exist.

Upon completion of clinical trials, a company seeking FDA approval to market a new non-biological drug must file a new drug application, or NDA, with the FDA. In addition to reports of the preclinical and clinical trials conducted under the U.S. IND application, the NDA includes information pertaining to the preparation of the drug substance, analytical methods, drug product formulation, detail on the manufacture of finished products and proposed product packaging and labeling. In addition to reports of the preclinical and clinical trials conducted under the U.S. IND application, the marketing application also includes other data and information relating to the product’s safety and efficacy. The manufacturing facility must also pass an FDA current Good Manufacturing Practices (cGMP) inspection before the marketing application can be approved.

A company seeking FDA approval to market a biological drug is required to prepare and submit additional information for inclusion in a single biologics license application, or BLA, which is similar in content to the NDA. To approve a BLA, the FDA must determine that the product is effective and that the manufacturing establishment and product meet applicable requirements to ensure the safety, purity, and potency of the product.

Submission of a standard NDA or BLA does not assure FDA approval for marketing. After the application is submitted, the FDA initially determines whether all pertinent data and information have been submitted before accepting the application for filing. After the application is considered filed, the FDA begins its substantive review. The FDA also typically will request a review and recommendation by an advisory committee consisting of outside experts. The FDA may accept or reject the advisory committee’s recommendations, or accept them with modifications. The application review process generally takes one to three years to complete, although reviews of non-biological drugs and biological drugs that meet a medical need for serious or life-threatening diseases may be accelerated or prioritized for a six month review. However, the process may take substantially longer if, among other things, the review is complex, the information is not complete, or the FDA has questions or concerns about the safety or efficacy of a product. In order to gain approval, the FDA may require post-marketing studies to be conducted and may impose other conditions as well. Expedited or accelerated approvals may require additional larger confirmatory clinical studies to be conducted following approval.

In addition, the FDA may, in some circumstances, impose restrictions on the use of the non-biological drug or biological product that may be difficult and expensive to administer. Product approval may be withdrawn if compliance with regulatory requirements is not maintained or if adverse events are reported after the product reaches the market. The FDA requires reporting of certain safety and other information that becomes known to a manufacturer of an approved non-biological drug or biological product. These reports may be voluntarily provided to the company and/or the FDA by physicians and other healthcare professionals. Manufacturing and sale may also be disrupted, or delayed, in the event of failure to comply with all required current Good Manufacturing Practices as determined by FDA investigators in periodic inspections of manufacturing facilities. In addition, changes in the product or the manufacturing facility may require the submission of a supplemental NDA or BLA.

Upon approval, a prescription non-biological drug or biological product may only be marketed for the approved indications in the approved dosage forms and at the approved dosage. In addition, the nature of marketing claims that we will be permitted to make in the labeling and advertising of our products will be limited to those specified in an FDA clearance or approval. Claims exceeding those that are cleared or approved will constitute violation of the Food, Drug and Cosmetic Act.

### ***Orphan Drug Act***

Under the Orphan Drug Act, a sponsor of a marketing application may seek to obtain a seven-year period of marketing exclusivity for a non-biological or biological drug intended to treat a rare disease or condition, which is defined as a disease or condition that occurs in fewer than 200,000 patients. Orphan drugs provide significant tax advantages to a sponsor. Before a product can receive marketing exclusivity associated with orphan product status, it must receive orphan product designation. If a drug is designated as an orphan drug or biologic by the FDA, the sponsor of the first FDA approved application of the drug or biologic for the specified indication receives seven years of marketing exclusivity, subject to certain limitations.

Millennium & ILEX Partners, L.P. has obtained orphan product designation for the CAMPATH® monoclonal antibody for the treatment of patients with chronic lymphocytic leukemia. We may seek such designation for other products as well. However, other companies may also receive orphan designation and obtain the FDA marketing approval before we obtain such approval. If another company obtains marketing approval for the same drug or biologic first and receives seven-year marketing exclusivity, we would not be permitted by the FDA to market our product in the United States for the same use during the exclusivity period. In addition, we could incur substantial costs in asserting any rights to prevent such uses we may have under the Orphan Drug Act. If we receive seven-year marketing exclusivity, FDA may rescind the period of exclusivity under certain circumstances, including our failure to assure a sufficient quantity of the drug.

The Orphan Drug Act is subject to amendment by Congress, which has periodically considered amendments that would change the substantive provisions of the law, including the market exclusivity provisions. There can be no assurance that the market exclusivity provisions under this Act will still be the same when the CAMPATH® monoclonal antibody or other product candidates are approved.

### ***Foreign Regulations***

We will also be subject to a variety of foreign regulations governing clinical trials and sales of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval.

### ***Other Regulations***

In addition to regulations enforced by the FDA, we also are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Millennium's research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for storing, handling, using and disposing of such materials comply with the standards prescribed by applicable regulations, the risk of accidental contaminations or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could have a material adverse effect.

### ***Regulation of Diagnostics***

The FDA regulates the development, manufacture, and marketing of medical devices including diagnostic products and reagents. The FDA has regulations that set varying requirements for medical devices according to potential risk class. Class I devices represent the lowest potential risk devices and are therefore subject only to the general controls that include establishment registration, product listing, the prohibition of mislabeling or adulteration, and a requirement to comply with current federal Good

Manufacturing Practices regulations. Premarket notification is required for some Class I clinical diagnostic devices. Class II devices present greater risk than Class I devices and are subject to special controls, such as guidelines or performance standards, as well as the same general controls that are applicable to Class I devices. Class II devices require premarket clearance to demonstrate to the FDA the manufacturer's claims that the device is substantially equivalent to other legally marketed devices, and meets generally accepted performance criteria that may be required to demonstrate that the device is safe and effective. Class III devices present a higher level of risk and are additionally subject to rigorous demonstration of safety and effectiveness through the premarket approval process.

For some Class I and most Class II devices, a premarket notification must be submitted to the FDA. Usually within 90 days of the receipt of this notification, the FDA makes the determination whether the device submitted is substantially equivalent to a legally marketed predicate device. A legally marketed predicate device is one which was marketed prior to the passage of the Medical Device Amendments of 1976, or a post-1976 device that has been determined by the FDA to be substantially equivalent to the previously cleared devices. A determination of substantial equivalence requires several FDA findings: First, that the device has the same intended use as the legally marketed device; and second, either that the device has the same technological characteristics as the legally marketed predicate device, or, if it does not, that the device is as safe and effective as the legally marketed predicate device and does not present different questions about safety and effectiveness. Class III devices require extensive clinical testing to prove safety and effectiveness, and submission of the resulting data to the FDA as a premarket approval application, or PMA. The FDA ordinarily will refer a new device PMA to an advisory panel of outside experts for a recommendation on whether to approve the application or to request additional testing.

Where a PMA is required, FDA regulations require the demonstration of safety and effectiveness, typically based upon extensive clinical trials. Fulfilling the requirements of the PMA are costly and both the preparation and review are time consuming, commonly taking from one to several years. Before granting premarket approval, the FDA must inspect and find acceptable the proposed manufacturing procedures and facilities. The FDA can also impose conditions of approval, such as requirements for postmarketing study, or restrictions on sale, distribution or use. The premarket approval regulations also require FDA approval of most changes made after the tests have been approved.

Analyte specific reagents, or ASRs, that are used by clinical laboratories to conduct in-house assays or "home brew" tests are regulated by FDA under this device classification scheme, and their sale, distribution, and use are restricted under FDA regulations. The majority of ASRs are Class I and exempt from premarket notification requirements, although they remain subject to other FDA requirements such as good manufacturing practices, labeling, and reporting. Some ASRs are Class II (for example, for blood bank tests) or Class III (for example, for HIV and tuberculosis tests) and are subject to FDA premarket review. ASRs for genetic testing or predictive genetic testing currently are Class I and exempt from premarket review, although FDA has announced that the agency may propose additional regulation of genetic tests if determined appropriate following its ongoing evaluation of pertinent reports and recommendations.

### ***Manufacturing Regulation***

The manufacture of diagnostic products and reagents must be in accordance with quality system regulations and current federal Good Manufacturing Practices regulations. Diagnostic products and reagents are also subject to various postmarketing requirements, such as complaint handling and reporting of adverse events. Premarket approval products are also subject to annual reports. The FDA typically inspects manufacturing facilities every two years.

### *Clinical Laboratory Improvement Amendments of 1988*

All medical testing in the United States is regulated by the Health Care Financing Administration according to the complexity of the testing as specified under the Clinical Laboratory Improvement Amendments of 1988. CLIA regulations establish three categories of laboratory tests, for which regulatory requirements become increasingly stringent as the complexity of the test rises: (1) tests that require little or no operator skill, which allows for a certificate waiver of the regulations; (2) tests of moderate complexity; and (3) high complexity tests which require significant operator skill or training. Complexity categorization of diagnostic tests has been the responsibility of the Centers for Disease Control and Prevention although that responsibility has recently been transferred to the FDA. CLIA regulatory requirements apply to facilities such as clinical laboratories, hospitals, and physician offices which perform laboratory tests. All laboratories are subject to periodic inspection. In addition, all laboratories performing tests of moderate or high complexity must register with HCFA or an organization to whom HCFA has delegated such authority. They also must meet requirements relating to personnel qualifications, proficiency testing, quality assurance, and quality control. We expect all genetic tests to be categorized as having moderate to high complexity. "Home brew" tests using analyte specific reagents must be conducted in a clinical laboratory meeting the requirements for high-complexity tests. In practical terms, performing a test of high complexity means that the individual supervising the test (generally, the physician, pathologist or laboratory director) must be appropriately educated and trained, and the laboratory must be certified for high complexity testing under CLIA.

### *State Regulation*

In addition to federal regulation, certain diagnostic tests will be subject to a variety of state laws and regulations in those states where our products may be marketed, sold or used. States also impose requirements on clinical laboratories and regulate the ordering of laboratory tests, reporting of test results and confidentiality of medical records.

### **Manufacturing**

We have limited manufacturing capabilities and ourselves produce only a few of our compounds for research and development and preclinical testing. We rely on third parties to manufacture most of our compounds for research, development, preclinical and clinical trials. We generally expect to rely on our collaborators or other third parties to maintain current Good Manufacturing Practices and to manufacture the products for which we obtain regulatory approval to market and sell. Our partnership with ILEX Products has entered into a supply agreement with Boehringer Ingelheim for the production of the CAMPATH® monoclonal antibody. Under most of our collaboration agreements, our collaborators have the exclusive right to manufacture products that result from their programs.

### **Sales and Marketing**

We do not currently have significant sales or marketing capabilities.

We expect to rely on our strategic collaborators or on other third parties to market most products that we may develop. For example, our partnership for the CAMPATH® product candidate has entered into a distribution agreement with Schering AG and its affiliate, Berlex Laboratories, to distribute the CAMPATH® product candidate on a worldwide basis, other than the Far East.

At some time in the future, we plan to co-promote or ourselves market several of the products that we may develop. We will be required to incur significant additional expenditures in building sales, marketing and commercial infrastructure to support this effort.

## **Competition**

We face intense competition from a wide range of pharmaceutical, biotechnology and diagnostic companies, as well as academic and research institutions and government agencies. Our competitors include organizations that are pursuing the same or similar technologies as those which constitute our technology platform and from organizations that are pursuing pharmaceutical or diagnostic products that are competitive with our potential products. Many of our competitors compete against us for strategic collaborators for their research and development and commercialization programs.

Principal competitive factors in our industry include:

- the quality and breadth of an organization's technology;
- the skill of an organization's employees and its ability to recruit and retain skilled employees;
- an organization's intellectual property estate;
- the range of capabilities from target identification and validation to drug discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development and commercialization activities.

We believe that the quality and breadth of our technology platform, the skill of our employees and our ability to recruit and retain skilled employees, our aggressive program of seeking patent protection for gene discoveries, our capabilities for early stage research and drug discovery and our capital resources are competitive strengths. However, many large pharmaceutical and biotechnology companies have significantly larger intellectual property estates than we do, more substantial capital resources than we have, and greater capabilities and experience than we do in preclinical and clinical development, sales, marketing, manufacturing and regulatory affairs.

## **Employees**

As of December 31, 2000, we had approximately 1,330 full-time employees, of whom approximately 400 hold Ph.D. or M.D. degrees and approximately 340 hold other advanced degrees. Approximately 1,070 of our employees are engaged in research and development activities and approximately 260 are engaged in business development, finance, operations support and administration. None of our employees is represented by a collective bargaining agreement, nor have we experienced work stoppages. We believe that relations with our employees are good.

## **RISK FACTORS THAT MAY AFFECT RESULTS**

This Annual Report on Form 10-K, together with the accompanying letter to shareholders, contains forward-looking statements, including statements about our growth and future operating results, discovery and development of products, potential acquisitions, strategic alliances and intellectual property. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We often use the words “believes,” “anticipates,” “plans,” “expects,” “intends” and similar expressions to help identify forward-looking statements.

There are a number of important factors that could cause Millennium’s actual results to differ materially from those indicated or implied by forward-looking statements. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this Form 10-K. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

### ***REGULATORY RISKS***

**We have not yet received marketing approval for any product or service resulting from our development efforts and may not be able to obtain any such approval.**

We have completed development of only one product candidate, the CAMPATH® monoclonal antibody, which we developed in our partnership with ILEX Products, Inc. In December 1999, this partnership applied to the U.S. Food and Drug Administration for approval to market this product. On February 20, 2001, the FDA issued a Class I complete response letter. However, it is possible that the FDA will not grant this marketing approval or, in order to gain approval, the FDA may require post-marketing studies or larger confirmatory clinical studies to be conducted and may impose other conditions and restrictions that may be difficult and expensive to administer.

All of the products that we are developing will require additional research and development, extensive preclinical studies and clinical trials and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, and expensive. In some cases, the length of time that it takes for us to achieve various regulatory approval milestones affects the payments that we are eligible to receive under our strategic alliance agreements.

We may need to successfully address a number of technological challenges in order to complete development of our products. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

**We have only limited experience in regulatory affairs, and some of our products may be based on new technologies; these factors may affect our ability or the time we require to obtain necessary regulatory approvals.**

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals. Moreover, certain of the products that are likely to result from our research and development programs may be based on new technologies and new therapeutic approaches that have not been extensively tested in humans. The regulatory requirements governing these types of products may be more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with any products that we develop based on these new technologies or new therapeutic approaches.

## ***RISKS RELATING TO OUR INDUSTRY, BUSINESS AND STRATEGY***

**Because discovering drugs based upon genomics is new, it is possible that this discovery process will not result in commercial products or services.**

The process of discovering drugs based upon genomics is new and evolving rapidly. We focus our genomics research primarily on diseases that may be linked to several or many genes working in combination. Both we and the general scientific and medical communities have only a limited understanding relating to the role of genes and their products in these diseases. To date, we have not commercialized any products or services, and we may not be successful in doing so in the future. In addition, relatively few products based on gene discoveries have been developed and commercialized by others. Rapid technological development by us or others may result in compounds, products or processes becoming obsolete before we recover our development expenses.

**Our plan to grow through acquisitions of other companies will not be successful if we are unable to integrate acquired companies with our other operations or if the technology or personnel of acquired companies do not meet our expectations.**

We completed our merger with LeukoSite, Inc. on December 22, 1999. In addition, on July 27, 2000 we acquired the business of Cambridge Discovery Chemistry Limited, a subsidiary of Oxford Molecular Group plc. We may not be able to successfully integrate or profitably manage these businesses. In addition, the combination of our business with these businesses may not achieve revenues, net income or loss levels, efficiencies or synergies that justify the merger. The combined company may experience slower rates of growth as compared to the historical rates of growth of Millennium and these businesses independently. We plan to make additional acquisitions in the future, which will entail similar risks.

**Competition for scientific and managerial personnel in our industry is intense; we will not be able to sustain our operations and grow if we are not able to attract and retain key personnel.**

Our success substantially depends on the ability, experience and performance of our senior management and other key personnel. If we lose one or more of the members of our senior management or other key employees, our business and operating results could be seriously harmed.

In addition, our future success will depend heavily on our ability to continue to hire, train, retain and motivate additional skilled managerial and scientific personnel. The pool of personnel with the skills that we require is limited. Competition to hire from this limited pool is intense.

**We face substantial competition, which may result in others discovering, developing or commercializing products and services before or more successfully than we do.**

The fields of genomics, biotechnology and pharmaceuticals are highly competitive. Many of our competitors are substantially larger than we are and have substantially greater capital resources, research and development staffs and facilities than we have. Furthermore, many of our competitors are more experienced than we are in drug discovery, development and commercialization, obtaining regulatory approvals and product manufacturing and marketing. As a result, our competitors may identify genes associated with diseases or discover, develop and commercialize products or services based on such genes before we do. In addition, our competitors may discover, develop and commercialize products or services that render non-competitive or obsolete the products or services that we or our collaborators are seeking to develop and commercialize.

**We may not be able to obtain biological material, including human and animal DNA samples, required for our genetic studies, which could delay or impede our drug discovery efforts.**

Our gene identification strategy includes genetic studies of families and populations prone to particular diseases. These studies require the collection of large numbers of DNA samples from



affected individuals, their families and other suitable populations as well as animal models. The availability of DNA samples and other biological material is important to our ability to discover the genes responsible for human diseases through human genetic approaches and other studies. Competition for these resources is intense. Access to suitable populations, materials and samples could be limited by forces beyond our control, including governmental actions. Some of our competitors may have obtained access to significantly more family and population resources and biological materials than we have obtained. As a result, we may not be able to obtain access to DNA samples necessary to support our human gene discovery programs.

***RISKS RELATING TO OUR FINANCIAL RESULTS AND STRUCTURE AND NEED FOR FINANCING***

**We have incurred substantial losses and expect to continue to incur losses. We will not be successful unless we reverse this trend.**

We have incurred losses in five of the last seven years. We expect to continue to incur substantial operating losses in future periods. To date, substantially all of our revenues have resulted from payments from collaborators. We have not received any revenues from the sale of products or clinical or diagnostic services.

We expect to increase our spending significantly as we continue to expand our infrastructure, research and development programs and commercialization activities. As a result, we will need to generate significant revenues to pay these costs and achieve profitability. We cannot be certain whether or when we will become profitable because of the significant uncertainties with respect to our ability to generate revenues from the sale of products and services and from existing and potential future strategic alliances.

**Our substantial indebtedness may adversely affect our cash flow and operations and be difficult for us to repay, which could adversely affect the value of your investment in us.**

We have substantial amounts of outstanding indebtedness. As of December 31, 2000, this consisted primarily of \$95,927,000 of 5.50% convertible subordinated notes due January 15, 2007. We also may obtain additional long-term debt and working capital lines of credit. As a result of this indebtedness, we have substantial principal and interest payment obligations. We may be unable to generate cash sufficient to pay the principal of, interest on and other amounts due in respect of our indebtedness when due.

Our substantial leverage could have significant negative consequences, including:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash from operations to service our indebtedness, thereby reducing the amount of our cash available for other purposes, including capital expenditures;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a possible competitive disadvantage vis-a-vis less leveraged competitors and competitors that have better access to capital resources.

**We may need additional financing, which may be difficult to obtain. Our failure to obtain necessary financing or doing so on unattractive terms could adversely affect our discovery and development programs and other operations.**

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our potential products. We will also require substantial funds to meet our obligations to our collaborators and maximize the prospective benefits to us from these alliances,

manufacture and market any products and services that are approved for commercial sale and meet our debt service obligations. Additional financing may not be available when we need it or may not be available on terms that are favorable to us.

If we are unable to obtain adequate funding on a timely basis, we may be required to significantly curtail one or more of our discovery or development programs. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain of our technologies, product candidates or products which we would otherwise pursue on our own.

### ***RISKS RELATING TO COLLABORATORS***

**We depend significantly on our collaborators to develop and commercialize products and services based on our work. Our business may suffer if any of our collaborators breaches its agreement or fails to support or terminates its alliance with us.**

We conduct most of our discovery and development activities through strategic alliances. The success of these programs depends heavily on the efforts and activities of our collaborators. Each of our collaborators has significant discretion in determining the efforts and resources that they will apply to the alliance. Our existing and any future alliances may not be scientifically or commercially successful.

The risks that we face in connection with these alliances include:

- All of our strategic alliance agreements are subject to termination under various circumstances, including, in many cases, on short notice without cause.
- In our strategic alliance agreements, we generally agree not to conduct specified types of research and development in the field that is the subject of the alliance. These agreements may have the effect of limiting the areas of research and development we may pursue, either alone or in collaboration with third parties.
- Our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products and services that are the subject of the alliance with us.
- Our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries.
- We will rely on our collaborators to manufacture most products covered by our alliances. For example, Becton Dickinson has the sole right to develop, manufacture and commercialize our Melastatin® gene detection product. Therefore, we cannot control the timing of the introduction of this product.

**We may not be successful in establishing additional strategic alliances, which could adversely affect our ability to develop and commercialize products and services.**

An important element of our business strategy is entering into strategic alliances for the development and commercialization of products and services based on our discoveries. We face significant competition in seeking appropriate collaborators. Moreover, these alliance arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish additional strategic alliances or other alternative arrangements. The terms of any additional strategic alliances or other arrangements that we establish may not be favorable to us. Moreover, such strategic alliances or other arrangements may not be successful.

## ***RISKS RELATING TO INTELLECTUAL PROPERTY***

**If we are unable to obtain patent protection for our discoveries, the value of our technology and products will be adversely affected. If we infringe patent or other intellectual property rights of third parties, we may not be able to develop and commercialize our products and services or the cost of doing so may increase.**

Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions.

Our ability to develop and commercialize products and services depends in significant part on our ability to:

- obtain patents;
- obtain licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect trade secrets.

**There is significant uncertainty about the validity and permissible scope of genomics patents in our industry, which may make it difficult for us to obtain patent protection for our discoveries.**

The validity and permissible scope of patent claims in the pharmaceutical and biotechnology fields, including the genomics field, involve important unresolved legal principles and are the subject of public policy debate in the United States and abroad. For example, there is significant uncertainty both in the United States and abroad regarding the patentability of gene sequences in the absence of functional data and the scope of patent protection available for full-length genes and partial gene sequences. Moreover, certain groups have made certain gene sequences available in publicly accessible databases. These and other disclosures may adversely affect our ability to obtain patent protection for gene sequences claimed by us in patent applications that we file subsequent to such disclosures. There is also some uncertainty as to whether human clinical data will be required for issuance of patents for human therapeutics. If such data are required, our ability to obtain patent protection could be delayed or otherwise adversely affected.

**Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our development and commercialization costs, or prevent us from developing or marketing our products or services.**

We may not have rights under some patents or patent applications related to our proposed products, processes or services. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, such as those described below, to develop, manufacture, sell or import certain of our proposed products, processes or services, we or our collaborators may choose to seek, or be required to seek, licenses under third party patents issued in the United States and abroad or those that might issue from United States and foreign patent applications. In such event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products, processes or services.

With respect to our product candidate LDP-01, we are aware of third party patents and patent applications which relate to certain anti-CD18 antibodies and their use in various methods of treatment including methods of reperfusion therapy and methods of treating focal ischemic stroke. In addition, our LDP-01, LDP-02, and CAMPATH® product candidates are humanized monoclonal antibodies. We

are aware of third party patents and patent applications that relate to certain humanized or modified antibodies, products useful for making humanized or modified antibodies, and processes for making and using humanized or modified antibodies. We are also aware of third party patents and patent applications relating to certain manufacturing processes, products thereof and materials useful in such processes.

Our product candidates LDP-341 and LDP-519 are small molecule drug candidates. With respect to LDP-341, we are aware of third party patents or patent applications that relate to either intermediates or synthetic processes used in the synthesis of this compound. Additionally, for the use of LDP-341 and LDP-519 in the treatment of infarctions we are aware of the existence of a potentially interfering patent application filed by one of our former consultants.

**We may become involved in expensive patent litigation or other proceedings, which could result in our incurring substantial costs and expenses or substantial liability for damages or require us to stop our development and commercialization efforts.**

There has been substantial litigation and other proceedings regarding the patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights. For example, we believe that we hold patent applications that cover genes that are also claimed in patent applications filed by others. Interference proceedings before the United States Patent and Trademark Office may be necessary to establish which party was the first to invent these genes.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our products, processes or services without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

#### ***RISKS RELATING TO PRODUCT MANUFACTURING, MARKETING AND SALES***

**Because many of the products and services that we develop will be based on new technologies and therapeutic approaches, the market may not be receptive to these products and services upon their introduction.**

The commercial success of any of our products and services that may be approved for marketing will depend upon their acceptance by physicians, patients, third party payors, reimbursors and governments as clinically useful, cost effective and safe. Many of the products and services that we are developing are based upon new technologies or therapeutic approaches. As a result, it may be more difficult for us to achieve market acceptance of our products and services, particularly the first products and services that we introduce to the market based on new technologies and therapeutic approaches. Our efforts to educate the medical community on these potentially unique approaches may require greater resources than would be typically required for products and services based on conventional technologies or therapeutic approaches.

**Because we have limited sales, marketing or distribution experience and capabilities, we will depend on third parties to successfully perform these functions on our behalf or will be required to incur significant costs and devote significant efforts to develop these capabilities.**

We have limited sales, marketing or distribution experience and capabilities. We plan to rely significantly on sales, marketing and distribution arrangements with our collaborators and other third parties for the products and services that we are developing. For example, our partnership that holds the CAMPATH® monoclonal antibody will rely solely upon Schering AG and its U.S. affiliate, Berlex Laboratories, for the marketing, distribution and sale of the CAMPATH® product candidate throughout the world other than the Far East. If in the future we elect to perform sales, marketing and distribution functions ourselves, we would face a number of additional risks, including the need to recruit experienced marketing and sales personnel.

**Because we have limited manufacturing capabilities, we will be dependent on third-party manufacturers to manufacture products for us or will be required to incur significant costs and devote significant efforts to establish our own manufacturing facilities and capabilities.**

We have limited manufacturing experience and no commercial scale manufacturing capabilities. In order to continue to develop products and services, apply for regulatory approvals and, ultimately, commercialize any products and services, we will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon third parties to produce material for preclinical testing purposes and expect to continue to do so in the future. We also expect to rely upon other third parties, including our collaborators, to produce materials required for clinical trials and for the commercial production of certain of our products if we succeed in obtaining necessary regulatory approvals. Our partnership with ILEX Products relies on Boehringer Ingelheim as the sole source manufacturer of the CAMPATH® monoclonal antibody.

There are a limited number of manufacturers that operate under the FDA's good manufacturing practices regulations capable of manufacturing for us. As a result, we have experienced some difficulty finding manufacturers for our products with adequate capacity for our anticipated future needs. If we are unable to arrange for third party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

We may in the future elect to manufacture certain of our products in our own manufacturing facilities. We will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

**If we fail to obtain an adequate level of reimbursement for our future products or services by third party payors, there may be no commercially viable markets for our products or services.**

The availability and levels of reimbursement by governmental and other third party payors affect the market for any pharmaceutical product or healthcare service. These third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. In certain foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. We may not be able to sell our products and services profitably if reimbursement is unavailable or limited in scope or amount.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system. Further proposals are likely. The potential for adoption of these proposals affects or will affect our ability to raise capital, obtain additional collaborators and market our products.

If we or our collaborators obtain marketing approvals for our products and services, we expect to experience pricing pressure due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

**Ethical, legal and social issues related to genetic testing may cause our diagnostic products to be rejected by customers or prohibited or curtailed by governmental authorities.**

Diagnostic tests that evaluate genetic predisposition to disease raise issues regarding the use and confidentiality of the information provided by such tests. Insurance carriers and employers might discriminate on the basis of such information, resulting in a significant barrier to the acceptance of such tests by customers. This type of discrimination could cause governmental authorities to prohibit or limit the use of such tests.

**Item 2. PROPERTIES**

We lease a total of approximately 710,000 square feet of laboratory and office space in several buildings located in Cambridge, Massachusetts, with the majority of this space subject to long term leases expiring in 2003, 2004, 2008, 2011, 2013 and 2014. We have signed two long term leases for two buildings to be constructed in Cambridge, each building consisting of approximately 200,000 square feet of office and laboratory space, expiring in 2019 and 2020. We expect to occupy the first of these buildings in Q3 2002 and the second building in Q3/Q4 2003.

In addition to our Cambridge, Massachusetts properties, we lease approximately 22,000 square feet of laboratory and office space in Cambridge, England for our subsidiary, Millennium Pharmaceuticals Limited under leases expiring in 2001 and 2002. In February 2001, we signed an agreement to lease a building to be constructed in Cambridge, England comprising 90,000 square feet of office and laboratory space which we expect to occupy in early 2003 and which will replace our current Cambridge, England location. This agreement for lease includes options for expansion into additional space at the same location.

We believe our currently-leased and occupied facilities, and the facilities to be constructed in Cambridge, Massachusetts and Cambridge, England, are suitable and adequate to meet our requirements for the near term.

**Item 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the last quarter of the year ended December 31, 2000.

## EXECUTIVE OFFICERS OF THE COMPANY

The following table sets forth the names, ages and positions of our executive officers.

<u>Name</u>	<u>Age</u>	<u>Positions Held</u>
Mark J. Levin . . . . .	50	Chairman of the Board of Directors, President and Chief Executive Officer
Kenneth J. Conway . . . . .	52	Senior Vice President and President of MPMx
John B. Douglas III . . . . .	47	Senior Vice President and General Counsel
Paul R. Hamelin . . . . .	46	Senior Vice President, Commercial Operations
Steven H. Holtzman . . . . .	47	Chief Business Officer
John Maraganore, Ph.D. . . . .	38	Senior Vice President, Strategic Product Development
Linda K. Pine . . . . .	49	Senior Vice President, Human Resources
Kevin P. Starr . . . . .	38	Senior Vice President and Chief Financial Officer
Robert Tepper, M.D. . . . .	45	Senior Vice President and Chief Scientific Officer
Susan J. Ward, Ph.D. . . . .	45	Senior Vice President, Strategy Leadership

*Mr. Levin* has served as our Chairman of the Board of Directors since March 1996, as our Chief Executive Officer since November 1994 and as a director of the Company since its inception. From 1987 to 1994, Mr. Levin was a partner at Mayfield, a venture capital firm, and co-director of its Life Science Group. While employed with Mayfield, Mr. Levin was the founding Chief Executive Officer of several biotechnology and biomedical companies, including Cell Genesys Inc., Stem Cells, Inc. (formerly CytoTherapeutics Inc.), Tularik Inc. and Focal, Inc. Mr. Levin holds an M.S. in Chemical and Biomedical Engineering from Washington University. Mr. Levin also serves on the Board of Directors of StemCells, Inc. and Tularik, Inc.

*Mr. Conway* has served as President and Founder of Millennium Predictive Medicine, Inc., a subsidiary of the Company that now operates as an unincorporated division of the Company, since September 1997. He served more than 26 years with Chiron Diagnostics Corporation (formerly Ciba Corning), a medical diagnostics company, most recently as Senior Vice President and General Manager of Immuno Diagnostics from 1996 to 1997. Previously, Mr. Conway was a Member of the Office of the President while President of the U.S. group of Chiron from 1991 to 1996. Other positions he held at Chiron include Vice President of several business units, as well as Vice President of manufacturing at the former Corning Medical.

*Mr. Douglas* has served as our General Counsel since May 1999 and Senior Vice President since June 2000. Prior to joining us, Mr. Douglas was engaged in the private practice of law as a sole practitioner and as a partner at the Boston law firm of Hutchins, Wheeler & Dittmar from October 1997 until May 1999. Mr. Douglas was previously Senior Vice President and General Counsel of Apple Computer, Inc., a computer hardware company, from January to October 1997. Mr. Douglas was Senior or Executive Vice President and General Counsel of Reebok International Ltd., a sports and fitness products company, from 1994 to January 1997, and was responsible for several other corporate staff functions for most of this period, including Real Estate, Tax, Human Resources and Public Affairs, and he was Vice President and General Counsel of Reebok from 1986 to 1994. Mr. Douglas received his J.D. from Harvard Law School and his A.B. from Colgate University.

*Mr. Hamelin* joined the Company in December 2000 as our Senior Vice President, Commercial Operations. Most recently Mr. Hamelin served as Senior Vice President, Global Medical Marketing for Pharmacia/Monsanto, a global pharmaceutical company, from June 1999 to November 2000. He served as Vice President Global Marketing for Searle/Monsanto, a pharmaceutical company, from 1997 to

1999. From 1995 to 1996, Mr. Hamelin served as General Manager and Vice President of Worldwide CV Franchise for Searle/Monsanto.

*Mr. Holtzman* has served as Chief Business Officer of the Company since May 1994. From 1986 to 1993, Mr. Holtzman was with DNX Corporation, a biomedical company, and its subsidiaries. He was founder and first employee of DNX, where he served as a member of the Board of Directors and Executive Vice President. Mr. Holtzman received his graduate B.Phil. degree in Philosophy from Oxford University, which he attended as a Rhodes Scholar. Mr. Holtzman currently serves as the sole biotechnology and pharmaceutical industry representative appointed to the National Bioethics Advisory Commission and is a member of the Board of Trustees of the Hastings Center.

*Dr. Maraganore* was appointed Senior Vice President, Strategic Product Development of the Company in December 2000 after serving as Vice President, Strategic Product Development from June 2000 to December 2000. He served as our Vice President, Strategic Planning and M&A from December 21, 1999 to June 2000. From July 1997 to December 21, 1999, he served as a director and from May 1997 to December 21, 1999, he served as Vice President and General Manager, of Millennium BioTherapeutics Inc., a majority-owned subsidiary of the Company which merged into the Company on December 21, 1999. Dr. Maraganore served from 1987 to 1997 at Biogen, Inc., a biopharmaceutical company, serving from 1995 to 1997 as Director of Marketing and Business Development and from 1992 to 1995 as Director of Biological Research. Dr. Maraganore received his Ph.D. from the University of Chicago.

*Ms. Pine* has served as Senior Vice President, Human Resources of the Company since October 1994. From 1990 to 1994, Ms. Pine served as Vice President of Consulting Services for The Survey Group, a regional human resources survey and consulting firm. From 1982 to 1990, she was Vice President of Human Resources and Corporate Relations with Collaborative Research, Inc. (now Genome Therapeutics Corporation). She earned her B.A. from Brandeis University and her M.P.A. from Northeastern University.

*Mr. Starr* has served as Chief Financial Officer of the Company since December 1998 and Senior Vice President since June 2000. From March 1998 to December 1998, he served as the Vice President, Finance of Millennium BioTherapeutics, Inc., while it was a majority-owned subsidiary of Millennium. Prior to joining Millennium BioTherapeutics, Mr. Starr held the positions of Corporate Controller and Manager of Financial Analysis at Biogen from 1991 to 1998. Mr. Starr holds a B.A. degree in mathematics and business from Colby College and an M.S. degree in corporate finance from Boston College.

*Dr. Tepper* has served as Senior Vice President of the Company since June 2000 and Chief Scientific Officer of the Company since March 1999. He joined us in August 1994 as Director, Biology, served as Vice President, Biology from January 1996 to November 1997 and served as Chief Scientific Officer, Pharmaceuticals from November 1997 to March 1999. From 1990 to 1994, Dr. Tepper served as Director of the Laboratory of Tumor Biology at Massachusetts General Hospital Cancer Center where he was the recipient of a Lucille P. Markey Biomedical Scholar award. Dr. Tepper is also a founder and member of the Scientific Advisory Board of Cell Genesys Inc. Dr. Tepper received his M.D. from Harvard Medical School and completed his residency in medicine at Massachusetts General Hospital where he was Chief Resident.

*Dr. Ward* has served as our Senior Vice President, Strategy Leadership since April 2000. Most recently she was Vice President, Project Management, Wyeth-Ayerst Research, the principal pharmaceutical research and development division of American Home Products Corporation, from 1997 to 2000. Previously, she served as Vice President CNS Disorders at Wyeth-Ayerst Research, UK, from 1993 to 1995, then as Vice President, Strategy at Wyeth-Ayerst from 1995 to 1997. She also served as head of Neuroscience and Inflammation Discovery at Sterling-Winthrop, a pharmaceutical company, from 1982 to 1993.



**Item 5. MARKET FOR THE COMPANY’S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

**(a) Market Price of and Dividends on Millennium’s Common Stock and Related Stockholder Matters**

Our Common Stock is traded on the Nasdaq National Market under the symbol “MLNM”. The following table reflects the range of the reported high and low last sale prices on the Nasdaq National Market for the periods indicated.

	2000		1999	
	High	Low	High	Low
First quarter . . . . .	\$78.64	\$29.12	\$ 9.53	\$ 6.36
Second quarter . . . . .	72.09	26.19	10.09	7.50
Third quarter . . . . .	78.49	48.13	19.35	9.19
Fourth quarter . . . . .	86.50	41.44	35.42	15.56

On February 28, 2001, the closing price per share of our Common Stock was \$33.75, as reported on the Nasdaq National Market and we had approximately 600 stockholders of record.

We have never declared or paid any cash dividends on our Common Stock. We anticipate that, in the foreseeable future, we will continue to retain any earnings for use in the operation of our business and will not pay any cash dividends.

On February 28, 2000 and September 7, 2000, the Board of Directors of the Company declared two-for-one stock splits of our Common Stock. These stock splits were effected in the form of 100% stock dividends paid on April 18, 2000 and October 4, 2000, respectively, to stockholders of record as of March 28, 2000 and September 27, 2000, respectively. All references to per share amounts have been restated to reflect these stock splits.

## Item 6. SELECTED FINANCIAL DATA

### Millennium Pharmaceuticals, Inc.

#### Selected Financial Data

	Year Ended December 31,				
	1996	1997	1998	1999	2000
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Revenue under strategic alliances . . . . .	\$ 31,764	\$ 89,933	\$133,682	\$ 183,679	\$ 196,269
Costs and expenses:					
Research and development . . . . .	34,803	74,828	114,190	159,877	268,740
General and administrative . . . . .	7,973	16,517	24,419	32,896	49,315
Amortization of intangibles . . . . .	—	2,397	2,702	3,816	55,123
Acquired in-process R&D . . . . .	—	83,800	—	350,503	—
	<u>42,776</u>	<u>177,542</u>	<u>141,311</u>	<u>547,092</u>	<u>373,178</u>
Loss from operations . . . . .	(11,012)	(87,609)	(7,629)	(363,413)	(176,909)
Other income (expense), net . . . . .	2,244	6,387	17,967	11,453	29,834
Debt conversion expense . . . . .	—	—	—	—	(54,852)
Income (loss) before cumulative effect of change in accounting principle(1) . . . . .	(8,768)	(81,222)	10,338	(351,960)	(201,927)
Cumulative effect of change in accounting principle(1) . . . . .	—	—	—	—	(107,692)
Net income (loss) . . . . .	(8,768)	(81,222)	10,338	(351,960)	(309,619)
Deemed preferred stock dividend . . . . .	—	—	—	(27,944)	(45,668)
Net income (loss) attributable to common stockholders . . . . .	<u>\$ (8,768)</u>	<u>\$ (81,222)</u>	<u>\$ 10,338</u>	<u>\$(379,904)</u>	<u>\$ (355,287)</u>
<b>Amounts per common share:</b>					
Income (loss) before cumulative effect of change in accounting principle, basic(2,3) . . . . .	\$ (0.10)	\$ (0.72)	\$ 0.09	\$ (2.42)	\$ (1.05)
Cumulative effect of change in accounting principle . . . . .	—	—	—	—	(0.56)
Deemed preferred stock dividend . . . . .	—	—	—	(0.19)	(0.23)
Net income (loss) attributable to common stockholders, basic(2,3) . . . . .	<u>\$ (0.10)</u>	<u>\$ (0.72)</u>	<u>\$ 0.09</u>	<u>\$ (2.61)</u>	<u>\$ (1.84)</u>
Weighted average shares, basic(2,3) . . . . .	<u>86,788</u>	<u>113,292</u>	<u>121,276</u>	<u>145,412</u>	<u>192,835</u>
Net income (loss) attributable to common stockholders, diluted(2,3) . . . . .	<u>\$ (0.10)</u>	<u>\$ (0.72)</u>	<u>\$ 0.08</u>	<u>\$ (2.61)</u>	<u>\$ (1.84)</u>
Weighted average shares, diluted(2,3) . . . . .	<u>86,788</u>	<u>113,292</u>	<u>126,032</u>	<u>145,412</u>	<u>192,835</u>
<b>Pro forma amounts assuming the accounting change is applied retroactively:</b>					
Net loss attributable to common stockholders . . . . .	<u>\$ (8,487)</u>	<u>\$(117,415)</u>	<u>\$(10,461)</u>	<u>\$(417,147)</u>	<u>\$ (247,595)</u>
Net loss per weighted share attributable to common stockholders, basic and diluted . . . . .	<u>\$ (0.10)</u>	<u>\$ (1.04)</u>	<u>\$ (0.09)</u>	<u>\$ (2.87)</u>	<u>\$ (1.28)</u>
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities . . . . .	\$ 63,848	\$ 96,557	\$190,964	\$ 261,716	\$1,452,367
Total assets . . . . .	87,744	144,513	257,954	541,625	1,811,922
Capital lease obligations, net of current portion . . . . .	9,308	19,809	24,827	27,488	29,369
Long-term debt . . . . .	—	—	—	—	95,927
Stockholders' equity . . . . .	66,639	91,755	206,362	439,406	1,462,283

(1) The cumulative effect of change in accounting principle is a one-time, noncash charge relating to Millennium's adoption of Staff Accounting Bulletin No. 101 ("SAB 101"). SAB 101 was issued by the Securities and Exchange Commission ("SEC") in December 1999. SAB 101 provides guidance related to revenue recognition policies based on interpretations and practices followed by the SEC. The impact of Millennium's adoption of SAB 101 was to defer revenue recognition for certain portions of the revenue previously recognized by Millennium under its strategic alliances into future accounting periods. Refer to Note 6 of the 2000 consolidated financial statements.

(2) Pro forma in 1996.

(3) All per share data have been restated to reflect the two-for-one stock splits of Millennium's Common Stock in the form of 100% stock dividends that were paid on April 18, 2000 and October 4, 2000, respectively.

## **Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Overview**

Millennium Pharmaceuticals, Inc. was founded in 1993. We incorporate large-scale genetics, genomics, high throughput screening, and informatics in an integrated science and technology platform, which we apply primarily in discovering and developing proprietary therapeutic and diagnostic human healthcare products and services.

During 2000, we expanded our operations through internal growth, additional strategic alliances and acquisitions. We also hired additional staff in research and drug discovery, informatics, biotherapeutics and diagnostics/prognostics, as well as in other support areas.

We currently derive our revenue primarily from payments from strategic alliances with major pharmaceutical companies. We have not received any revenue from the sale of products. Significant strategic alliances include the following: two agreements with the Wyeth-Ayerst Division of American Home Products ("AHP") in certain disorders of the central nervous system and in bacterial diseases, respectively; an agreement with Bayer, AG ("Bayer") in cardiovascular disease, and certain areas of oncology, osteoporosis, pain, liver fibrosis, hematology and viral infections; a research alliance and technology transfer agreement with Monsanto Company ("Monsanto") in plant agriculture; a technology transfer agreement and joint development and commercialization agreement with Aventis Pharmaceuticals, Inc. ("Aventis") in inflammatory disease; Millennium and ILEX Partners, L.P. ("M&I"), a joint venture partnership with ILEX Products, Inc. ("ILEX") for development of the CAMPATH® (alemtuzumab) product candidate, a monoclonal antibody for use in the treatment of chronic lymphocytic leukemia, for which the partnership is currently seeking approval from the Food and Drug Administration ("FDA"); and an agreement, through our joint venture partnership with ILEX, with Schering AG for distribution of the CAMPATH® product candidate. In addition, we have a number of other strategic alliances. Our strategic alliance agreements have provided us with various combinations of equity investments, license fees and research funding, and may provide certain additional payments contingent upon our attainment of research and regulatory milestones and royalty and/or profit sharing payments based on sales of any products resulting from the collaborations.

In December 2000, the Oncologic Drugs Advisory Committee (ODAC) to the FDA recommended accelerated approval of M&I's CAMPATH® product candidate. In February 2001, M&I received a Class I complete response letter from the FDA. In the letter, the FDA indicated that the timeframe for accelerated approval has been extended for a 60-day period. M&I expects to complete ongoing discussions with the FDA on final package labeling and design of a post-marketing confirmatory study for the CAMPATH® product during this time.

Our goal is to become an integrated biopharmaceutical company. As a result, we expect to continue to pursue additional alliances and to consider joint development, merger, or acquisition opportunities that may provide us with access to products on the market or in later stages of commercial development than those represented within our current programs. We expect that we will incur increasing expenses and may incur increasing operating losses for at least the next several years, primarily due to expansion of facilities and research and development programs and as a result of our efforts to advance acquired products or our own development programs to commercialization. Our results of operations for any period may not be indicative of future results because our revenues under strategic alliance and licensing arrangements and from product sales, to the extent that we receive product sales in future periods, may fluctuate from period to period or year to year.

## Results of Operations

### Years Ended December 31, 2000 and December 31, 1999

Effective October 1, 2000, we changed our method of accounting for revenue recognition in accordance with Staff Accounting Bulletin (SAB) No. 101 (“SAB 101”), *Revenue Recognition in Financial Statements*. Previously, we had recognized revenue relating to non-refundable, up-front, license and milestone payments and certain research funding payments from our strategic partners in accordance with the contract. Under the new accounting method adopted retroactively to January 1, 2000, we now recognize revenue from non-refundable, up-front, license and milestone payments, not specifically tied to a separate earnings process, ratably over the term of the research contract. When payments are specifically tied to a separate earnings process, revenue is recognized when earned. In addition, when appropriate, we recognize revenue from certain research payments based upon the level of research services performed during the research contract. The cumulative effect of the change resulted in a charge to income of \$107.7 million and relates to revenue previously recognized by us that was deferred into future periods. The pro forma amounts presented in the consolidated statements of operations were calculated assuming the accounting change was made retroactively to prior periods. Included in 2000 revenue is \$20.0 million of revenue that was recognized in prior years relating to the adoption of SAB 101. The amount of revenue to be recognized in future years that was included in the cumulative effect of change in accounting principle is \$41.6 million, \$37.3 million, \$9.2 million and \$.5 million in 2001, 2002, 2003 and 2004, respectively.

The following discussions relating to the net loss attributable to common stockholders and revenue for the year ended December 31, 2000 (the “2000 Period”) and the net loss attributable to common stockholders and revenue for the year ended December 31, 1999 (the “1999 Period”) reflect pro forma results as if we had followed SAB 101 from our inception.

For the 2000 Period, we had a net loss attributable to common stockholders of \$247.6 million or \$1.28 per basic and diluted share compared to a net loss attributable to common stockholders of \$417.1 million or \$2.87 per basic and diluted share for the 1999 Period. Operating results for the 2000 Period represent the first reported year of fully combined revenues and expenses related to our acquisition of LeukoSite, Inc. (“LeukoSite”) and five months of combined revenues and expenses related to our acquisition of Cambridge Discovery Chemistry Ltd. (“CDC”).

Revenue under strategic alliances increased to \$196.3 million for the 2000 Period from \$146.4 million for the 1999 Period. The increase is primarily attributable to revenue from a new alliance with Aventis, other new alliance revenue and an increase in the revenue recognized under the Bayer alliance during the 2000 Period. Revenues may fluctuate from period to period and we cannot assure you that strategic alliance agreements will continue for their initial term or beyond.

Research and development expenses increased to \$268.7 million for the 2000 Period from \$159.9 million for the 1999 Period. The increase was primarily attributable to our continued investment in clinical trials and preclinical product candidates, increased personnel and facilities expenses, increased purchases of laboratory supplies, increased technology license payments and increased professional fees. Research and development expenses for the 2000 Period represent the first reported year of fully combined expenses related to the acquisition of LeukoSite and five months of combined expenses related to the acquisition of CDC. We expect research and development expenses to continue to increase as we add personnel and expand our research and development activities to accommodate our existing and future strategic alliances and development efforts to move our product candidates to commercialization.

General and administrative expenses increased to \$49.3 million for the 2000 Period from \$32.9 million for the 1999 Period. The increase was primarily attributable to increased expenses for additional management and administrative personnel associated with the expansion and increased complexity of our operations and business development efforts. General and administrative expenses for the 2000 Period represent the first reported year of fully combined expenses related to the acquisition of LeukoSite and five months of combined expenses related to the acquisition of CDC. We expect general and administrative expenses to continue to increase as we add capabilities to support the further advancement of our development efforts.

On December 22, 1999, we acquired LeukoSite for an aggregate purchase price of \$550.4 million, primarily consisting of 26,707,732 shares of Common Stock and 3,536,348 shares of Common Stock issuable upon the exercise of assumed LeukoSite options and warrants. We recorded the transaction as a purchase for accounting purposes and accordingly, we allocated the purchase price to the assets purchased and liabilities assumed based upon their respective fair values. We allocated the excess of the purchase price over the estimated fair market value of net tangible assets to specific intangible assets and goodwill. We are amortizing intangible assets and goodwill on a straight-line basis over four years. Amortization expense for the 2000 Period of \$55.1 million is primarily related to the LeukoSite acquisition. We also recorded a one-time, noncash charge to operations in 1999 of \$350.5 million for acquired in-process research and development. With respect to the value of the purchased research and development, we considered, among other factors, the research and development project's stage of completion, the complexity of the work completed to date, the costs already incurred, the projected costs to complete, the contribution of core technologies and other acquired assets, the projected date to market and the estimated useful life. We then discounted the respective after-tax cash flows back to present value using a risk-adjusted discount rate. As of December 31, 2000, the status of our research and development projects acquired is expected to continue in line with our original estimates set forth in the 1999 Period. Our ability to successfully complete the research and development projects will be dependent upon numerous factors over which we may have limited or no control. If we do not successfully develop these projects, we may not realize the value assigned to the in-process technology. Additionally, the value of the other intangible assets acquired may also become impaired.

On July 27, 2000, we acquired CDC, a subsidiary of Oxford Molecular Group, plc, for an aggregate purchase price of \$50.0 million in cash. We recorded the transaction as a purchase for accounting purposes and accordingly, we allocated the purchase price to the assets purchased and liabilities assumed based upon their respective fair values. We allocated the excess of the purchase price over the estimated fair market value of tangible assets acquired and liabilities assumed to intangible assets, resulting in \$5.5 million of specific intangible assets and \$48.9 million of goodwill. The acquisition did not result in an in-process research and development charge. We are amortizing intangible assets and goodwill on a straight-line basis over four years. We expect the acquisition to provide us with the capabilities in medicinal and computational chemistry necessary to accelerate our downstream drug discovery efforts.

Through our 1999 acquisition of LeukoSite, we became a party to a joint venture partnership (M&I) with ILEX for development of the CAMPATH® product candidate. Under the terms of the partnership, we are required to fund fifty percent of M&I's working capital requirements. We account for our investment in the joint venture under the equity method of accounting. Equity in operations of the joint venture was a loss of \$5.4 million for the 2000 Period. The loss is primarily attributable to pre-product launch marketing and sales activities.

Interest income increased to \$55.0 million for the 2000 Period from \$12.5 million for the 1999 Period. The increase resulted primarily from a higher level of invested funds due to net proceeds from our public stock offering in October 2000 of \$767.4 million (including the underwriters' exercise of their over-allotment option) and \$388.7 million in net proceeds from our convertible debt offering which closed in January 2000. Interest expense increased to \$19.7 million for the 2000 Period from \$3.0 million for the 1999 Period due to increased obligations arising primarily from the convertible debt.

During the 2000 Period, we paid an aggregate of \$54.9 million in cash to certain holders of our convertible notes in order to induce the conversion of their notes into our Common Stock. These cash payments were expensed during the 2000 Period.

The minority interest in 2000 includes the minority shareholder interest of Becton, Dickinson and Company ("Becton Dickinson") in the net income for the 2000 Period of our then majority-owned subsidiary, Millennium Predictive Medicine, Inc. ("MPMx"). On June 2, 2000, we acquired the outstanding Preferred and Common Stock of our MPMx subsidiary that we did not already own, making MPMx a wholly-owned subsidiary of the Company. We recorded a deemed preferred stock dividend of \$45.7 million in 2000 relating to the excess of the fair value of our Common Stock over the carrying value of the MPMx minority interest acquired from Becton Dickinson.

The minority interest of \$2.0 million in 1999 includes the minority shareholder interest of Eli Lilly and Company ("Lilly") in the net loss for the 1999 Period of our then majority-owned subsidiary, Millennium BioTherapeutics, Inc. ("MBio"), as well as the minority shareholder interest of Becton Dickinson in the net income for the 1999 Period of our then majority-owned subsidiary, MPMx. In October 1999, we issued Lilly approximately 1,500,000 shares of Millennium Common Stock in exchange for all MBio shares owned by it. In December 1999, we merged MBio with and into Millennium. We recorded a deemed preferred stock dividend of \$27.9 million in 1999 relating to the excess of the fair value of our Common Stock over the carrying value of the MBio minority interest acquired from Lilly.

#### **Years Ended December 31, 1999 and December 31, 1998**

The following discussions relating to the net loss attributable to common stockholders and revenue for the 1999 Period and the net loss and revenue for the year ended December 31, 1998 (the "1998 Period") reflect pro forma results as if we had followed SAB 101 from our inception.

For the 1999 Period we had a net loss attributable to common stockholders of \$417.1 million or \$2.87 per basic and diluted share, as compared to a net loss of \$10.5 million or \$0.09 per basic share and diluted share for the 1998 Period.

Revenue under strategic alliances increased to \$146.4 million for the 1999 Period from \$112.9 million for the 1998 Period. The increase is primarily attributable to a full year of revenue under the Bayer alliance as compared to two months of Bayer revenue in the 1998 Period.

Research and development expenses increased to \$159.9 million for the 1999 Period from \$114.2 million for the 1998 Period. The increase was primarily attributable to increased personnel and facilities expenses, increased purchases of laboratory supplies, costs of external collaborations and increased equipment depreciation.

General and administrative expenses increased to \$32.9 million for the 1999 Period from \$24.4 million for the 1998 Period. The increase was primarily attributable to increased expenses for additional management and administrative personnel, as well as to increased facilities expenses, consulting, and other professional fees associated with the expansion and increased complexity of our operations and business development efforts.

On December 22, 1999, we acquired LeukoSite for an aggregate purchase price of \$550.4 million primarily consisting of 26,707,732 shares of Common Stock and 3,536,348 shares of Common Stock issuable upon the exercise of LeukoSite options and warrants. We recorded the transaction as a purchase for accounting purposes and the consolidated financial statements include LeukoSite's operating results from the date of the acquisition. We allocated the purchase price, based upon an independent valuation, to the assets purchased and liabilities assumed based upon their respective fair values, with the excess of the purchase price over the estimated fair market value of net tangible assets allocated to in-process research and development, assembled workforce, core technology and goodwill.

We are amortizing amounts allocated to goodwill, assembled workforce, and core technology on a straight-line basis over a period of four years. The 1999 amortization expense related to these intangibles was \$1.1 million. We incurred a one-time, noncash charge to operations in 1999 of \$350.5 million for acquired in-process research and development. The valuation of acquired in-process research and development represents the estimated fair value related to incomplete projects that, at the time of the acquisition, had no alternative future use and for which technological feasibility had not been established.

The cost approach was used to value assembled workforce. This approach establishes the fair value of an asset by calculating the recruiting and loss of productivity costs avoided by obtaining a pre-existent, trained, and fully efficient team. The income approach was used to establish the fair values of core technology and in-process research and development. This approach establishes the fair value of an asset by estimating the after-tax cash flows attributable to the asset over its useful life and then discounting these after-tax cash flows back to a present value.

With respect to the value of purchased research and development, we considered, among other factors, the research and development project's stage of completion, the complexity of the work completed to date, the costs already incurred, the projected costs to complete, the contribution of core technologies and other acquired assets, the projected date to market and the estimated useful life. The respective after-tax cash flows were then discounted back to present value using a risk-adjusted discount rate. The discount rates used in the LeukoSite analysis ranged from 19% to 23<sup>1</sup>/<sub>4</sub>%, depending upon the risk profile of the asset.

We believed and continue to believe that the assumptions used to value the acquired intangibles were reasonable at the time of the acquisition. We cannot assure you, however, that the underlying assumptions we used to estimate projected revenues, development costs or profitability, or other events associated with such projects, will transpire as estimated. For these reasons, among others, actual results may vary from the projected results.

The in-process technology we acquired from LeukoSite consisted of five significant research and development projects with values assigned of \$14.8 million to \$136.3 million for each project. These include humanized monoclonal antibodies for the treatment of refractory chronic lymphocytic leukemia, inflammatory bowel disease and the prevention of post-ischemic reperfusion, small molecule chemotherapeutic agents, and a small molecule compound for treatment of bronchial asthma. Acquired in-process technologies related to preclinical projects consisted of treatments primarily for inflammatory and autoimmune conditions and diseases, as well as treatments for asthma and allergies and were assigned a value of \$85.8 million. Through the acquisition date, LeukoSite had spent approximately \$150 million on in-process research and development projects. We expect to incur approximately \$10 million to \$45 million for each of the four remaining significant projects and approximately

\$45 million for all of the projects in preclinical development to develop the in-process technology into commercially viable projects.

The estimated stage of completion for acquired research and development projects ranged from 45% to 95%. Of the five projects acquired, one project reached completion in late 1999 with the filing of a BLA, while the others, which are in various stages of Phase I and Phase II clinical trials, are expected to reach completion in 2003 through 2006. The first of the molecules comprising the preclinical development portfolio is expected to reach completion in 2006. To successfully complete the aforementioned projects we will be required to undertake and complete a number of significant activities, including product validation, the successful completion of clinical trials and governmental regulatory approvals.

Our ability to successfully complete the research and development projects will be dependent upon numerous factors over which we may have limited or no control. If these projects are not successfully developed, we may not realize the value assigned to the in-process technology. Additionally, the value of the other intangible assets acquired may also become impaired.

Interest income increased to \$12.5 million for the 1999 Period from \$6.2 million for the 1998 Period. The increase resulted from an increase in our average balance of cash, cash equivalents and marketable securities. Interest expense increased to \$3.0 million for the 1999 Period from \$2.4 million for the 1998 Period due to increased capital lease obligations.

The minority interest of \$2.0 million in 1999 includes the minority shareholder interest of Lilly in the net loss for the 1999 Period of our then majority-owned subsidiary, MBio, as well as the minority shareholder interest of Becton Dickinson in the net income for the 1999 Period of our then majority-owned subsidiary, MPMx. In October 1999, we issued Lilly approximately 1,500,000 shares of Millennium Common Stock in exchange for all MBio shares owned by it. In December 1999, we merged MBio with and into Millennium. We recorded a deemed preferred stock dividend of \$27.9 million in 1999 relating to the excess of the fair value of our Common Stock over the carrying value of the MBio minority interest acquired from Lilly. The minority interest of \$14.2 million in 1998 represents the entire net loss of MBio. This loss is attributed completely to the minority stockholder because the minority stockholder provided all equity funding for MBio during 1998.

### **Liquidity and Capital Resources**

As of December 31, 2000, we had approximately \$1.5 billion in cash, cash equivalents and marketable securities, an increase of approximately \$1.2 billion from December 31, 1999. This excludes \$29.6 million of interest-bearing marketable securities classified as restricted cash on the balance sheet, which serve as collateral for letters of credit securing leased facilities.

The increase in cash, cash equivalents and marketable securities is primarily due to \$919.4 million of proceeds from sales of Common Stock and exercises of warrants, \$388.7 million of net proceeds from the convertible debt offering, \$75.7 million of proceeds from employee stock purchases relating to the exercise of options, offset by cash outflows of \$108.7 million for operating activities, \$51.8 million relating to the acquisition of CDC, purchases of \$31.6 million of property and equipment and other long term assets, and \$12.3 million to pay capital lease obligations.

In January 2000, we completed a sale, pursuant to Rule 144A of the Securities Act of 1933, of \$400.0 million of 5.5% convertible subordinated notes due January 15, 2007 which resulted in net proceeds of \$388.7 million. The notes are convertible into shares of our Common Stock at any time prior to maturity at a price equal to \$42.07 per share, subject to adjustment, unless previously repurchased or redeemed by us under certain circumstances. Under the terms of the notes, we are required to make semi-annual interest payments on the outstanding principal balance of the notes on January 15 and July 15 of each year. To date, all required interest payments have been made. The net



proceeds of this offering will be used for working capital and other corporate purposes including financing our growth, accelerating the expansion of our technology platform, developing products, including conducting preclinical testing and clinical trials, and acquisitions of businesses, products and technologies that complement or expand our business.

During the 2000 Period, we paid an aggregate of \$54.9 million in cash to certain holders of our convertible notes in order to induce the conversion of their notes into our Common Stock. These cash payments were expensed during the 2000 Period. These conversions resulted in the retirement of \$304.1 million of outstanding principal of our convertible notes, the issuance of approximately 7.2 million shares of our Common Stock, and the reclassification of deferred debt issuance costs of \$7.0 million to additional paid-in capital.

On June 23, 2000, we entered into an alliance with Aventis covering the joint development and commercialization of drugs for the treatment of inflammatory diseases; joint development of new drug discovery technologies; transfer of key elements of our technology platform to Aventis to enhance its existing capabilities; and purchase of an equity interest in us by Aventis. In North America, we have agreed to share the responsibility for and cost of developing, marketing and manufacturing products arising from the alliance, as well as profits. Outside of North America, Aventis is responsible for developing and marketing products arising from the alliance, with a royalty obligation to us. Under a Technology Transfer Agreement, we agreed to provide Aventis with rights to our drug discovery technologies in exchange for payments of up to \$200.0 million over a five-year period. Under an Investment Agreement, Aventis agreed to invest \$250.0 million in our Common Stock. As part of this \$250.0 million equity investment, Aventis made a \$150.0 million stock purchase in the third quarter of 2000 and made a \$50.0 million stock purchase in January 2001. Aventis is required to make an additional \$50.0 million stock purchase in July 2001.

On August 4, 2000, we entered into lease agreements, relating to two buildings to be constructed for laboratory and office space in Cambridge, Massachusetts. The rent obligation for each building is expected to commence on the earlier of (a) September 1, 2002 or October 1, 2003, respectively or (b) the date on which we commence occupancy of the respective building. Both leases are for a term of seventeen years. We are responsible for a portion of the construction costs for both buildings. The cost to complete one of the buildings is expected to be approximately \$31.0 million. The other building is currently in the design phase and construction costs are currently being estimated. Rent is calculated on an escalating scale ranging from approximately \$7.6 million, per building per year, to approximately \$9.7 million, per building per year.

On October 11, 2000, we completed a public offering of 11,000,000 shares of our Common Stock resulting in net proceeds to us of \$677.1 million. On October 17, 2000 the underwriters exercised their over-allotment option with respect to an additional 1,465,500 shares of Common Stock, resulting in net proceeds to us of an additional \$90.3 million. We plan to use the net proceeds of this offering for working capital and other corporate purposes including financing our growth, accelerating the expansion of our technology platform, developing products, including conducting preclinical testing and clinical trials, and acquisitions of businesses, products and technologies that complement or expand our business.

As of December 31, 2000, we had net operating loss carryforwards of approximately \$720.0 million to offset future federal taxable income expiring in 2004 through 2020 and \$660.0 million to offset future state taxable income expiring in 2001 through 2005. Due to the degree of uncertainty related to the ultimate realization of such prior losses, no benefit has been recognized in the financial statements as of December 31, 2000. We would allocate any subsequently recognized tax benefits to operations, goodwill and additional paid-in capital. Moreover, our ability to utilize these losses in future years may be limited under the change of stock ownership rules of the Internal Revenue Service.

We believe that existing cash, our investment securities and the anticipated cash payments from our current strategic alliances will be sufficient to support our operations and fund our capital commitments for the near term. Our actual future cash requirements, however, will depend on many factors, including the progress of our disease research programs, the number and breadth of these programs, achievement of milestones under strategic alliance arrangements, acquisitions, our ability to establish and maintain additional strategic alliance and licensing arrangements, the progress of our development efforts and the development efforts of our strategic partners, and our ability to repay our long-term debt at maturity.

We may require additional financing in the future, which we may seek to raise through public or private security offerings, debt financings, additional strategic alliances or other financing sources. However, additional financing, strategic alliances or licensing arrangements may not be available when needed or, if available, such financing may not be obtained on terms favorable to our stockholders or us.

### **Accounting Pronouncements**

In June 1998, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 133, “Accounting for Derivative Instruments and Hedging Activities.” The effective date of this statement was deferred to fiscal years beginning after June 15, 2000 by SFAS No. 137 “Accounting for Derivative Instruments and Hedging Activities—Deferral of Effective Date of SFAS No. 133.” SFAS No. 133 was amended by SFAS No. 138 “Accounting for Certain Derivative Instruments and Certain Hedging Activities.” We believe the adoption of this new accounting standard will not have a significant effect on our financial statements.

### **Subsequent Events**

In January 2001, Aventis made a \$50.0 million purchase of Millennium Common Stock pursuant to the Investment Agreement between Aventis and us.

In February 2001, we entered into an Agreement for Lease, relating to a building to be constructed for laboratory and office space in Cambridge, England. The lease is expected to have a 20 year term and to commence in 2003. We are responsible for a portion of the construction costs, which we estimate to be approximately \$21.0 million. Rent is expected to be approximately \$2.4 million per year and is subject to market adjustments at the end of the 5<sup>th</sup>, 10<sup>th</sup> and 15<sup>th</sup> years.

In February 2001, M&I received a Class I complete response letter from the FDA relating to the CAMPATH® product. In the letter, the FDA indicated that the timeframe for accelerated approval has been extended for a 60-day period. M&I expects to complete ongoing discussions with the FDA on final package labeling and design of a post-marketing confirmatory study for the CAMPATH® product during this time.

In March 2001, we entered into a strategic alliance with Abbott Laboratories. This alliance is for a five-year term, and is primarily for collaborative research and development in the area of metabolic diseases. We and Abbott have agreed to share equally the cost of developing, manufacturing and marketing products on a worldwide basis. Our arrangement with Abbott also includes a technology exchange and development agreement and an equity investment by Abbott, under which we are eligible to receive up to \$250 million. As part of this \$250.0 million equity investment, Abbott has agreed to make an initial investment of \$50.0 million in April 2001 and additional investments totalling \$200 million in seven quarterly installments from later in 2001 through 2003.

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We maintain an investment portfolio in accordance with our Investment Policy. The primary objectives of our Investment Policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our Investment Policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. A hypothetical 100 basis point increase in interest rates would result in an approximate \$21.1 million decrease in the fair value of our investments as of December 31, 2000. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments in our investment portfolio.

The interest rates on our convertible subordinated notes and capital lease obligations are fixed and therefore not subject to interest rate risk.

Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments which would require disclosure under this item.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Millennium Pharmaceuticals, Inc.  
Report of Independent Auditors**

Board of Directors and Stockholders  
Millennium Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Millennium Pharmaceuticals, Inc. as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Millennium Pharmaceuticals, Inc. at December 31, 2000 and 1999, and the consolidated results of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 2 to the consolidated financial statements, in 2000 the Company changed its method of accounting for revenue recognition.

Ernst & Young LLP

January 22, 2001  
Boston, Massachusetts

**Millennium Pharmaceuticals, Inc.**  
**Consolidated Balance Sheets**

	December 31,	
	2000	1999
	(in thousands, except per share amounts)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 166,086	\$ 56,775
Marketable securities . . . . .	1,286,281	204,941
Due from strategic alliance partners . . . . .	21,901	11,579
Prepaid expenses and other current assets . . . . .	11,312	13,215
Total current assets . . . . .	1,485,580	286,510
Property and equipment, net . . . . .	85,803	59,543
Restricted cash . . . . .	29,635	11,173
Other assets . . . . .	4,964	1,792
Goodwill, net . . . . .	177,083	161,125
Intangible assets, net . . . . .	28,857	21,482
Total assets . . . . .	\$1,811,922	\$ 541,625
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 20,256	\$ 22,953
Accrued expenses . . . . .	18,278	14,062
Acquisition related contingencies . . . . .	12,937	—
Obligation to fund joint venture . . . . .	8,653	3,244
Deferred revenue . . . . .	61,842	7,936
Current portion of capital lease obligations . . . . .	14,208	10,968
Total current liabilities . . . . .	136,174	59,163
Deferred revenue . . . . .	88,169	—
Capital lease obligations, net of current portion . . . . .	29,369	27,488
Long term debt . . . . .	95,927	—
Minority interest . . . . .	—	15,568
Commitments and contingencies		
Stockholders' Equity:		
Preferred Stock, \$0.001 par value; 5,000 shares authorized, none issued . . . . .	—	—
Common Stock, \$0.001 par value; 500,000 shares authorized: 213,979 shares in 2000 and 178,602 shares in 1999 issued and outstanding . . . . .	214	179
Additional paid-in capital . . . . .	2,203,902	883,035
Deferred compensation . . . . .	(1,296)	(1,055)
Notes receivable from officers . . . . .	(385)	(1,026)
Accumulated other comprehensive income (loss) . . . . .	10,455	(739)
Accumulated deficit . . . . .	(750,607)	(440,988)
Total stockholders' equity . . . . .	1,462,283	439,406
Total liabilities and stockholders' equity . . . . .	\$1,811,922	\$ 541,625

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

**Millennium Pharmaceuticals, Inc.**  
**Consolidated Statements of Operations**

	Year Ended December 31,		
	2000	1999	1998
	(in thousands, except per share amounts)		
Revenue under strategic alliances . . . . .	\$ 196,269	\$ 183,679	\$133,682
Costs and expenses:			
Research and development . . . . .	268,740	159,877	114,190
General and administrative . . . . .	49,315	32,896	24,419
Amortization of intangible assets . . . . .	55,123	3,816	2,702
Acquired in-process R&D . . . . .	—	350,503	—
	373,178	547,092	141,311
Loss from operations . . . . .	(176,909)	(363,413)	(7,629)
Equity in operations of joint venture . . . . .	(5,409)	—	—
Interest income . . . . .	54,987	12,511	6,198
Interest expense . . . . .	(19,681)	(3,038)	(2,410)
Debt conversion expense . . . . .	(54,852)	—	—
Minority interest . . . . .	(63)	1,980	14,179
Income (loss) before cumulative effect of change in accounting principle . . . . .	(201,927)	(351,960)	10,338
Cumulative effect of change in accounting principle . . . . .	(107,692)	—	—
Net income (loss) . . . . .	(309,619)	(351,960)	10,338
Deemed preferred stock dividend . . . . .	(45,668)	(27,944)	—
Net income (loss) attributable to common stockholders . . . . .	\$(355,287)	\$(379,904)	\$ 10,338
<b>Amounts per common share:</b>			
Income (loss) before cumulative effect of change in accounting principle . . . . .	\$ (1.05)	\$ (2.42)	\$ 0.09
Cumulative effect of change in accounting principle . . . . .	(0.56)	—	—
Deemed preferred stock dividend . . . . .	(0.23)	(0.19)	—
Net income (loss) attributable to common stockholders, basic . . . . .	\$ (1.84)	\$ (2.61)	\$ 0.09
Weighted average shares, basic . . . . .	192,835	145,412	121,276
Net income (loss) attributable to common stockholders, diluted . . . . .	\$ (1.84)	\$ (2.61)	\$ 0.08
Weighted average shares, diluted . . . . .	192,835	145,412	126,032
<b>Pro forma amounts assuming the accounting change is applied retroactively:</b>			
Net loss attributable to common stockholders . . . . .	\$(247,595)	\$(417,147)	\$(10,461)
Net loss per weighted share attributable to common stockholders, basic and diluted . . . . .	\$ (1.28)	\$ (2.87)	\$ (0.09)

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

**Millennium Pharmaceuticals, Inc.**  
**Consolidated Statements of Cash Flows**

	Year Ended December 31,		
	2000	1999	1998
	(in thousands)		
<b>Cash flows from operating activities:</b>			
Net income (loss) . . . . .	\$ (309,619)	\$(351,960)	\$ 10,338
Adjustments to reconcile net income (loss) to cash provided by (used in) operating activities:			
Acquired in-process R&D . . . . .	—	350,503	—
Depreciation and amortization . . . . .	79,346	20,951	16,284
Minority interest . . . . .	63	(1,980)	(14,179)
Net loss on asset disposal . . . . .	—	—	97
Stock compensation expense . . . . .	2,786	4,041	2,029
Equity in operations of joint venture . . . . .	5,409	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets . . . . .	5,669	(6,166)	(438)
Due from strategic alliance partners . . . . .	(9,722)	(4,919)	(5,882)
Restricted cash and other assets . . . . .	(18,388)	(1,126)	(6,276)
Accounts payable, accrued expenses and other . . . . .	(4,242)	9,993	5,645
Deferred revenue . . . . .	139,977	2,654	(552)
Net cash provided by (used in) operating activities . . . . .	(108,721)	21,991	7,066
<b>Cash flows from investing activities:</b>			
Investments in marketable securities . . . . .	(1,418,693)	(217,805)	(84,932)
Proceeds from sales and maturities of marketable securities . . . . .	348,856	84,950	59,606
Purchase of property and equipment and other long term assets . . . . .	(31,559)	(21,418)	(7,590)
Net cash used in Cambridge Discovery Chemistry Ltd. acquisition . . . . .	(51,835)	—	—
Net cash acquired in LeukoSite, Inc. acquisition . . . . .	—	11,234	—
Net cash used in investing activities . . . . .	(1,153,231)	(143,039)	(32,916)
<b>Cash flows from financing activities:</b>			
Issuance of convertible subordinated notes, net of issuance costs . . . . .	388,695	—	—
Proceeds from sales of common stock and exercises of warrants . . . . .	919,447	—	96,600
Proceeds from sale of subsidiary stock . . . . .	—	15,000	—
Net proceeds from employee stock purchases . . . . .	75,693	34,105	5,699
Principal payments on capital leases . . . . .	(12,263)	(9,566)	(7,401)
Net cash provided by financing activities . . . . .	1,371,572	39,539	94,898
<b>Increase (decrease) in cash and cash equivalents . . . . .</b>	<b>109,620</b>	<b>(81,509)</b>	<b>69,048</b>
Equity adjustment from foreign currency translation . . . . .	(309)	—	—
<b>Cash and cash equivalents, beginning of year . . . . .</b>	<b>56,775</b>	<b>138,284</b>	<b>69,236</b>
<b>Cash and cash equivalents, end of year . . . . .</b>	<b>\$ 166,086</b>	<b>\$ 56,775</b>	<b>\$138,284</b>
<b>Supplemental cash flow information:</b>			
Cash paid for interest . . . . .	\$ 17,043	\$ 3,038	\$ 2,410
<b>Supplemental disclosure of noncash investing and financing activities:</b>			
Equipment acquired under capital leases . . . . .	\$ 15,079	\$ 12,818	\$ 15,229
Deferred compensation relating to issuance of stock options . . . . .	1,160	1,059	—
Write off of capital assets . . . . .	1,453	—	—
Issuance of common stock to Abgenix, Inc. . . . .	10,000	—	—
Buyout of Becton Dickinson interest in MPMx, including deemed preferred stock dividend . . . . .	61,160	—	—
MPI buyout of common stock interest in MPMx . . . . .	82,400	—	—
Conversion of subordinated debt to common stock . . . . .	304,070	—	—
Acquisition and additional goodwill of Cambridge Discovery Chemistry Ltd. . . . .	2,178	—	—
Acquisition and additional goodwill of LeukoSite, Inc. including direct transaction costs of \$2,700 in 1999 . . . . .	15,880	550,371	—
Reclassification of debt issuance costs to additional paid-in capital . . . . .	7,021	—	—
Deemed preferred stock dividend resulting from MPI buyout of Eli Lilly interest in MBio . . . . .	—	27,944	—

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

**Millennium Pharmaceuticals, Inc.  
Statements of Stockholders' Equity**

(in thousands, except shares)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deferred Compensation	Notes Receivable from Officers	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 1997	116,677,592	\$116	\$ 193,167	\$ (1,992)	\$ (166)	\$ (4)	\$ (99,366)	\$ 91,755
Net income						33	10,338	10,338
Unrealized gain on marketable securities								33
Total comprehensive income								10,371
Issuance of common stock	19,830,640	20	96,580					96,600
Repurchase of common stock	(220,800)		(23)					(23)
Exercise of stock warrants	92,360							
Employee stock purchases	3,187,752	4	5,626					5,630
Forgiveness of notes from officers					79			79
Stock compensation expense			565					565
Write off deferred stock compensation			(182)	182				853
Stock compensation earned				853				532
401K stock match	125,272		532					
Balance at December 31, 1998	139,692,816	140	296,265	(957)	(87)	29	(89,028)	206,362
Net loss								(351,960)
Unrealized loss on marketable securities						(768)		(768)
Total comprehensive loss								(352,728)
Issuance of common stock	37,811,996	39	580,494					580,533
Repurchase of common stock	(10,828)		(1)					(1)
Exercise of stock warrants	504,456							
Employee stock purchases	491,524		2,226					2,226
Issuance of Common Stock in exchange for note from officer					(1,026)			(1,026)
Forgiveness of notes from officers					87			87
Deferred stock compensation			1,059	(1,059)				
Stock compensation expense			1,815					1,815
Write off deferred stock compensation			(33)	33				928
Stock compensation earned				928				1,210
401K stock match	112,504		1,210					
Balance at December 31, 1999	178,602,468	179	883,035	(1,055)	(1,026)	(739)	(440,988)	439,406
Net loss								(309,619)
Unrealized gain on marketable securities						11,503		11,503
Foreign currency translation						(309)		(309)
Total comprehensive loss								(298,425)
Issuance of common stock	17,548,846	17	944,987					945,004
Issuance of common stock pursuant to conversion of subordinated notes	7,227,689	7	297,055					297,062
Repurchase of common stock	(132,572)		(52)					(52)
Exercise of stock warrants	530,505	1	167					168
Employee stock purchases	10,153,296	10	75,683					75,693
Repayment of notes from officers					641			641
Deferred stock compensation			1,160	(1,160)				
Stock compensation expense				919				919
401K stock match	48,761		1,867					1,867
Balance at December 31, 2000	213,978,993	\$214	\$2,203,902	\$ (1,296)	\$ (385)	\$10,455	\$ (750,607)	\$1,462,283

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



**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2000**

**[1] The Company**

Millennium Pharmaceuticals, Inc. (“Millennium” or the “Company”) incorporates large-scale genetics, genomics, high throughput screening, and informatics in an integrated science and technology platform. Millennium applies this technology platform primarily in discovering and developing proprietary therapeutic and diagnostic human healthcare products and services.

**[2] Summary of Significant Accounting Policies**

**Basis of Presentation**

The consolidated financial statements include the accounts of Millennium and its majority-owned subsidiaries and other subsidiaries controlled by the Company. The ownership of the other interest holders of the consolidated subsidiaries is reflected as minority interest. There were no such other interest holders as of December 31, 2000. All significant intercompany accounts and transactions have been eliminated in consolidation. Investment in the Company’s unconsolidated joint venture is accounted for using the equity method (see Note 6).

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

**Cash Equivalents and Marketable Securities**

Cash equivalents consist principally of money market funds and corporate bonds with original maturities of three months or less at the date of purchase. Marketable securities consist of high-grade corporate bonds, asset-backed and U.S. government agency securities.

Management determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. Marketable securities at December 31, 2000 and 1999 are classified as “available-for-sale.” Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in a separate component of stockholders’ equity. The cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

There have been no significant realized gains or losses on sales of any marketable securities in 2000, 1999, and 1998.

**Concentrations of Credit Risk**

Cash and cash equivalents are primarily maintained with two major financial institutions in the United States. Deposits with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of marketable securities. Marketable securities consist of high-grade corporate bonds, asset-backed and U.S. government agency securities. The Company’s investment policy, approved by the Board of

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[2] Summary of Significant Accounting Policies (Continued)**

Directors, limits the amount the Company may invest in any one type of investment, thereby reducing credit risk concentrations.

**Segment Information**

The Company has identified three operating segments which, under the applicable provision of SFAS No. 131, have been aggregated into one reportable segment. Substantially all of the Company's revenues have been derived from its strategic alliances. Revenues from Aventis accounted for approximately 10% of consolidated revenues for the 2000 Period. Revenues from Bayer accounted for approximately 27%, 45% and 25% of consolidated revenues in the years 2000, 1999 and 1998, respectively. Revenues from Monsanto accounted for approximately 22%, 20% and 29% of consolidated revenues in the years 2000, 1999 and 1998, respectively. The 1999 and 1998 revenue percentages do not reflect the impact of SAB 101. There were no other significant customers in 2000, 1999 and 1998.

**Fair Value of Financial Instruments**

The carrying amounts reported in the Company's balance sheets for other current assets and long-term debt approximate their fair value. The fair values of the Company's long-term debt are estimated using discounted cash flow analyses based on the Company's current incremental borrowing rates for similar types of borrowing arrangements.

**Property and Equipment**

Property and equipment are stated at cost. Equipment consists principally of assets held under capitalized leases and those assets are stated at the present value of future minimum lease obligations. Application development costs incurred for computer software developed or obtained for internal use are capitalized in accordance with Statement of Position ("SOP") No. 98-1, "Accounting for the Costs of Computer Software Developed for Internal Use." Leasehold improvements are stated at cost and are amortized over the remaining life of the building lease. Depreciation is recorded on the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease as follows:

Equipment . . . . .	3 to 4 years
Capitalized software . . . . .	3 to 5 years
Leasehold improvements . . . . .	4 to 15 years

**Intangible Assets**

Intangible assets at December 31, 2000 consist of goodwill and other intangible assets. Amortization is computed using the straight-line method over the useful lives of the respective assets, generally four years. Amortization expense for all intangible assets was \$55.1 million, \$3.8 million, and \$2.7 million in 2000, 1999, and 1998, respectively. Accumulated amortization was \$64.0 million and \$8.9 million at December 31, 2000 and 1999, respectively. On a periodic basis, the Company estimates the future undiscounted cash flows of the businesses to which the intangible assets relate in order to ensure that the carrying value of such intangible assets has not been impaired.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[2] Summary of Significant Accounting Policies (Continued)**

**Revenue Recognition**

Effective October 1, 2000, Millennium changed its method of accounting for revenue recognition in accordance with Staff Accounting Bulletin (SAB) No. 101 ("SAB 101"), *Revenue Recognition in Financial Statements*. Previously, the Company had recognized revenue relating to non-refundable, up-front, license and milestone payments and certain research funding payments from its strategic partners in accordance with the contract. Under the new accounting method adopted retroactively to January 1, 2000, the Company recognizes revenue from non-refundable, up-front, license and milestone payments, not specifically tied to a separate earnings process, ratably over the term of the research contract. When payments are specifically tied to a separate earnings process, revenue is recognized when earned. In addition, when appropriate, the Company recognizes revenue from certain research payments based upon the level of research services performed during the period of the research contract. The cumulative effect of the change on prior years resulted in a charge to income of \$107.7 million, which is included in the loss for the year ended December 31, 2000.

**Income Taxes**

The liability method is used to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization.

**Net Income (Loss) Per Share**

Basic net income (loss) per common share is computed using the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed using the weighted average number of common and dilutive common equivalent shares from stock options, warrants and convertible debt using the treasury stock method. The 2000 and 1999 net loss attributable to common stockholders is calculated by including the deduction of a deemed preferred stock dividend relating to the excess of the fair value of the Company's common stock over the carrying value of the MPMx and MBio minority interests acquired, respectively. At December 31, 2000 and 1999, diluted net loss per share is the same as basic net loss per share, as the inclusion of outstanding Common Stock options, warrants and convertible debt would be antidilutive. At December 31, 1998, the difference between basic and diluted shares used in the computation of earnings per share is approximately 4.8 million weighted-average common stock equivalent shares resulting from outstanding Common Stock options and warrants.

**Stock Dividends**

On April 12, 2000, the Company filed a Certificate of Amendment of Certificate of Incorporation increasing the authorized Common Stock, \$0.001 par value per share, of the Company from 100,000,000 shares to 500,000,000 shares. On February 28, 2000 and September 7, 2000, the Board of Directors of the Company declared two-for-one stock splits of the Company's Common Stock. These stock splits were effected in the form of 100% stock dividends paid on April 18, 2000 and October 4, 2000, respectively, to stockholders of record as of March 28, 2000 and September 27, 2000, respectively. Stockholders' equity has been restated to give retroactive application to each stock split in prior periods by reclassifying from additional paid-in capital to Common Stock the par value of the additional shares

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[2] Summary of Significant Accounting Policies (Continued)**

arising from the stock splits. In addition, all references in the consolidated financial statements to the number of shares and per share amounts have been restated.

**Foreign Currency Translation**

For operations outside the U.S. that prepare financial statements in currencies other than the U.S. dollar, results of operations and cash flows are translated at average exchange rates during the period, and assets and liabilities are translated at end of period exchange rates. Foreign currency transaction gains and losses are included in the results of operations and are not material to the Company's consolidated financial statements. Translation adjustments are excluded from the determination of net loss and are accumulated in a separate component of accumulated other comprehensive income (loss) in stockholders' equity.

**Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income (loss), unrealized gains and losses on marketable securities and cumulative foreign currency translation adjustments. Accumulated other comprehensive income as of December 31, 2000 included \$10.8 million and \$0.3 million of unrealized gains on marketable securities and cumulative foreign currency translation adjustments, respectively. Comprehensive income (loss) is reflected in the consolidated statements of stockholders' equity.

**Stock-Based Compensation**

The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), in accounting for its stock-based compensation plans, rather than the alternative fair value accounting method provided for under Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation." Under APB 25, when the exercise price of options granted under these plans equals the market price of the underlying stock on the date of grant, no compensation expense is required. In accordance with Emerging Issues Task Force ("EITF") 96-18, the Company records compensation expense equal to the fair value of options granted to non-employees over the vesting period, which is generally the period of service.

**Accounting Pronouncements**

In June 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The effective date of this statement was deferred to fiscal years beginning after June 15, 2000 by SFAS No. 137 "Accounting for Derivative Instruments and Hedging Activities—Deferral of Effective Date of SFAS No. 133." SFAS No. 133 was amended by SFAS No. 138 "Accounting for Certain Derivative Instruments and Certain Hedging Activities." The Company believes the adoption of this new accounting standard will not have a significant effect on its financial statements.

**[3] Subsidiaries**

**Millennium BioTherapeutics, Inc.**

In May 1997, the Company established Millennium BioTherapeutics, Inc. ("MBio") as a subsidiary and, pursuant to a Technology Transfer and License Agreement, transferred and/or licensed certain technology to MBio in exchange for 9,000,000 shares of the subsidiary's Series A Convertible Preferred Stock. At that time, MBio entered into a strategic alliance with Eli Lilly and Company ("Lilly") for the

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[3] Subsidiaries (Continued)**

discovery and development of novel therapeutic proteins. Under the terms of a related stock purchase agreement, Lilly purchased \$20 million of Series B Convertible Preferred Stock of MBio for an approximate 18% equity interest in MBio. The accompanying consolidated financial statements for 1999 and 1998 include the accounts of MBio since inception. The minority interest in the accompanying consolidated statements of operations includes the minority stockholder's interest in the net loss of MBio for the years ended December 31, 1999 and 1998. In 1998, MBio's entire net loss was attributed completely to the minority stockholder because the minority stockholder provided all equity funding for MBio in 1998.

In October 1999, Lilly was issued approximately 1,500,000 shares of Millennium Common Stock in exchange for all shares of MBio Series B Convertible Preferred Stock owned by it. Also in October 1999, MBio amended the terms of its strategic alliance with Lilly. Under the amendment, the research program was refocused from the discovery of new therapeutic proteins to further development of the therapeutic proteins which had been identified in the course of the research program. In December 1999, MBio was merged with and into Millennium. The Company recorded a deemed preferred stock dividend of \$27.9 million in 1999 relating to the excess of the fair value of its Common Stock over the carrying value of the MBio minority interest acquired from Lilly.

The Company had entered into certain agreements with this subsidiary to provide specific services and facilities at negotiated fees. Such fees amounted to \$10.5 million and \$12.5 million in 1999 and 1998, respectively. The Company had subleased approximately \$0.6 million of equipment to MBio under an existing capital lease agreement. All such intercompany transactions have been eliminated in consolidation.

**Millennium Predictive Medicine, Inc.**

In September 1997, the Company established a wholly-owned subsidiary, Millennium Predictive Medicine, Inc. ("MPMx"), to develop products and services to optimize the prevention, diagnosis, treatment and management of disease. In February 1999, MPMx announced the formation of a strategic alliance in the diagnostic field with Becton, Dickinson and Company ("Becton Dickinson"). In March 1999, Becton Dickinson made an equity investment in MPMx of \$15.0 million, representing approximately an 11% voting interest in MPMx, and paid a \$3.0 million licensing fee to MPMx. The minority interest in the accompanying consolidated balance sheets represents the equity interest of Becton Dickinson in MPMx as of December 31, 1999 and the minority interest in the accompanying consolidated statements of operations includes the minority stockholder's interest in the net income of MPMx for the years ended December 31, 2000 and 1999. All intercompany transactions with this subsidiary have been eliminated in consolidation.

On June 2, 2000, the Company acquired the outstanding Preferred and Common Stock of its MPMx subsidiary that it did not already own, making MPMx a wholly-owned subsidiary of the Company. The transaction was a stock-for-stock merger. Under the terms of the agreement, MPMx shareholders, including Becton Dickinson, received 0.8 shares of Millennium Common Stock in exchange for each MPMx share. The total value of Millennium Common Stock received by MPMx's stockholders in the merger, based upon the fair value of Millennium Common Stock on the date of the announcement of the merger, March 2, 2000, was approximately \$143.6 million. The Company recorded a deemed preferred stock dividend of \$45.7 million in 2000 relating to the excess of the fair value of its Common Stock over the carrying value of the MPMx minority interest acquired from Becton Dickinson.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[4] LeukoSite Acquisition**

On December 22, 1999, the Company acquired LeukoSite, Inc. (“LeukoSite”) for an aggregate purchase price of \$550.4 million primarily consisting of 26,707,732 shares of Common Stock and 3,536,348 shares of Common Stock issuable upon the exercise of LeukoSite options and warrants. The value of the Common Stock issued in connection with this merger was calculated using a fair value of \$18.63 per share. This per share fair value represents the average closing price of the Company’s Common Stock when the merger was announced. Common Stock issuable upon exercise of LeukoSite options and warrants was assigned a fair value using the Black-Scholes method. The transaction was recorded as a purchase for accounting purposes and the consolidated financial statements include LeukoSite’s operating results from the date of the acquisition. The purchase price was allocated to the assets purchased and liabilities assumed based upon their respective fair values, with the excess of the purchase price over the estimated fair market value of net tangible assets allocated to specific intangible assets and goodwill as follows (in thousands):

Goodwill . . . . .	\$159,080
Assembled workforce . . . . .	2,920
Core technology . . . . .	18,712
In-process research and development . . . . .	<u>350,503</u>
Total Allocated to Intangibles . . . . .	<u>\$531,215</u>

During 2000, the Company determined that certain LeukoSite contingent liabilities related to previous acquisitions made by LeukoSite were probable. As a result, the Company accrued \$15.9 million of contingent liabilities through an increase to goodwill. Amounts allocated to goodwill, assembled workforce, and core technology are being amortized on a straight-line basis over a period of four years. Amortization expense related to these items was \$46.6 million and \$1.1 million in 2000 and 1999, respectively. The Company also incurred a one-time, noncash charge to operations in 1999 of \$350.5 million for acquired in-process research and development. The valuation of acquired in-process research and development represents the estimated fair value related to incomplete projects that, at the time of the acquisition, had no alternative future use and for which technological feasibility had not been established.

The cost approach was used to value assembled workforce. This approach establishes the fair value of an asset by calculating the recruiting and loss of productivity costs avoided by obtaining a pre-existent, trained, and fully efficient team. To calculate avoided recruiting costs, a unit cost for hiring an employee equivalent to each of those transferred to the Company was calculated and applied to each employee acquired. The avoided loss in productivity was calculated by quantifying the time required for an employee to reach full productivity and applying the amount to each employee’s total average cost.

The income approach was used to establish the fair values of core technology and in-process research and development. This approach establishes the fair value of an asset by estimating the after-tax cash flows attributable to the asset over its useful life and then discounting these after-tax cash flows back to a present value. The discounting process uses a rate of return commensurate with the time value of money and investment risk factors. Accordingly, for the purpose of establishing the fair value of core technology and in-process research and development, revenues for each future period were estimated, along with costs, expenses, taxes and other charges. Revenue estimates were based on

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[4] LeukoSite Acquisition (Continued)**

estimates of relevant market sizes and growth factors, expected trends in technology and the nature and expected timing of new product introductions by the Company and its competitors.

With respect to the value of purchased research and development, the Company considered, among other factors, the research and development project's stage of completion, the complexity of the work completed to date, the costs already incurred, the projected costs to complete, the contribution of core technologies and other acquired assets, the projected date to market and the estimated useful life. The respective after-tax cash flows were then discounted back to present value using a risk-adjusted discount rate. The discount rates used in the LeukoSite analysis ranged from 19% to 23¼%, depending upon the risk profile of the asset.

The most significant purchased research and developments projects that were in-process at the date of the acquisition consisted of a chemotherapeutic agent, a humanized monoclonal antibody for oncology and non-oncology indications, and 10 molecules in preclinical development. In aggregate these projects represented approximately 83% of the in-process value. The chemotherapeutic agent represented approximately 39% of the in-process research and development value. Key assumptions used in the analysis of the chemotherapeutic agent included gross margin of 95% and a discount rate of 22%. The chemotherapeutic agent is a new class of small molecules that acts by inhibiting the proteasome, the complex of a cell which regulates the breakdown of proteins that are critical for cell proliferation. As of the date of the acquisition, the project was expected to be completed and commercially available in the U.S. in 2006, with an estimated cost to complete of approximately \$15.0 to \$20.0 million. During 2000, the Company reprioritized and expanded its clinical development strategy for this chemotherapeutic agent and now believes the estimated costs to complete the original project are approximately \$40.0 million to \$45.0 million.

The humanized monoclonal antibody represented approximately 20% of the in-process research and development value. Key assumptions used in the analysis of this project included gross margins of 100%, as revenue is royalty based, and a discount rate of 19%. The primary indication for this humanized monoclonal antibody, CAMPATH®, relates to the treatment of refractory chronic lymphocytic leukemia for which Millennium & ILEX Partners, L.P. ("M&I") currently is seeking FDA approval. The antibody works by binding to an antigen found on leukemia cells, thus triggering their destruction. As of the date of the acquisition, the Biologics License Application ("BLA") for the CAMPATH® product was expected to be completed by the end of 1999 and the Company anticipated that the CAMPATH® product would be commercially available in the U.S. in 2000. In December 2000, the FDA Advisory Committee recommended accelerated approval of the CAMPATH® product. The clinical trials for the other indications for the humanized monoclonal antibody are expected to be completed and products commercially available in the U.S. between 2003 and 2004. As the BLA for the CAMPATH® product was near completion at the time of the acquisition and the clinical trials for the other indications build substantially on work already performed, the estimated cost to complete these projects was not considered to be significant at the time of acquisition, nor is it considered to be significant now.

The portfolio of molecules in preclinical development represented approximately 24% of the in-process research and development value. As these products are expected to be partnered, revenue will be royalty based. Therefore, gross margins of 100% were used in the analysis. The discount rate used in valuing the portfolio of preclinical molecules was 23¼%.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[4] LeukoSite Acquisition (Continued)**

Molecules in preclinical development relate primarily to treatments for inflammatory and autoimmune conditions and diseases, as well as treatments for asthma and allergies. Of the ten molecules in the preclinical portfolio, the first molecules are expected to be completed and commercially available in the U.S. in 2005 with the remaining molecules expected to be completed and commercially available in the U.S. between 2006 and 2008. At the date of acquisition and at December 31, 2000, the estimated cost to complete all projects in preclinical development was approximately \$40 to \$45 million.

The major risk associated with the timely completion and commercialization of these products is the ability to confirm the safety and efficacy of the technology based on the data of long-term clinical trials. If these projects are not successfully developed, future results of operations of the Company may be adversely affected. Additionally, the value of the other intangible assets acquired may become impaired.

The Company believes that the assumptions used to value the acquired intangibles and in-process research and development were reasonable at the time of the acquisition and remain reasonable at December 31, 2000. No assurance can be given, however, that the underlying assumptions used to estimate expected project revenues, development costs or profitability, or the events associated with such projects, will transpire as estimated. For these reasons, among others, actual results may vary from the projected results.

The following unaudited pro forma consolidated results of operations have been prepared as if the acquisition of LeukoSite had occurred on January 1, 1998 (in thousands, except per share amounts):

	<u>Year ended December 31,</u>	
	<u>1999</u>	<u>1998</u>
Pro Forma:		
Revenues under strategic alliances . . . . .	\$198,150	\$147,266
Costs and expenses . . . . .	<u>278,401</u>	<u>203,532</u>
Net loss . . . . .	<u>\$ (80,251)</u>	<u>\$ (56,266)</u>
Net loss per share . . . . .	\$ (0.47)	\$ (0.38)
Shares used in calculating net loss per share . .	171,464	147,584

The pro forma net loss and net loss per share amounts for each period above exclude the acquired in-process research and development charge and do not reflect the impact of SAB 101. The pro forma consolidated results do not purport to be indicative of results that would have occurred had the acquisition been in effect for the periods presented, nor do they purport to be indicative of the results that will be obtained in the future.

**[5] CDC Acquisition**

On July 27, 2000, the Company acquired Cambridge Discovery Chemistry Ltd. ("CDC"), a subsidiary of Oxford Molecular Group, plc, for an aggregate purchase price of \$50.0 million. The transaction was recorded as a purchase for accounting purposes and accordingly, the purchase price was allocated to the assets purchased and liabilities assumed based upon their respective fair values. The excess of the purchase price over the estimated fair market value of tangible assets acquired and



**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[5] CDC Acquisition (Continued)**

liabilities assumed was allocated to intangible assets resulting in \$5.5 million of specific intangible assets relating to contracts and assembled workforce and \$48.9 million of goodwill. The acquisition did not result in an in-process research and development charge. Intangible assets and goodwill are being amortized on a straight-line basis over four years. The Company has not presented pro forma results of operations as though CDC was acquired on January 1, 1999 because the pro forma results are not materially different than the actual results of operations recorded. The consolidated financial statements include CDC's operating results from the date of acquisition.

**[6] Revenues and Strategic Alliances**

The Company has formed strategic alliances with major participants in marketplaces where its discovery expertise and technology platform are applicable. These agreements include alliances based on the transfer of technology platforms, alliances which combine technology transfer with a focus on a specific disease or therapeutic approach, and disease-focused programs under which the Company conducts research funded by its partners. The Company's disease-based alliances and alliances which combine technology-transfer with a disease focus are generally structured as research collaborations. Under these arrangements, the Company performs research in a specific disease area aimed at discoveries leading to novel pharmaceutical (small molecule) products. These alliances generally provide research funding over an initial period, with renewal provisions, varying by agreement. Under these agreements, the Company's partners may make up-front payments, additional payments upon the achievement of specific research and product development milestones, ongoing research funding and/or pay royalties or in some cases profit-sharing payments to the Company based upon any product sales resulting from the collaboration.

Effective October 1, 2000, Millennium changed its method of accounting for revenue recognition in accordance with SAB 101. The cumulative effect of the change resulted in a charge to income of \$107.7 million and relates to revenue previously recognized by the Company that was deferred into future periods. The pro forma amounts presented in the consolidated statements of operations were calculated assuming the accounting change was made retroactively to prior periods. Included in the 2000 revenue is \$20.0 million of revenue that was recognized in prior years relating to the adoption of SAB 101. The amount of revenue to be recognized in future years that was included in the cumulative effect of change in accounting principle is \$41.6 million, \$37.3 million, \$9.2 million and \$.5 million in 2001, 2002, 2003 and 2004, respectively.

**Significant Alliances Beginning in 2000**

On June 23, 2000, the Company entered into an alliance with Aventis Pharmaceuticals Inc. ("Aventis"), the pharmaceutical company of Aventis S.A., covering the joint development and commercialization of drugs for the treatment of inflammatory diseases; joint development of new drug discovery technologies; transfer of key elements of the Company's technology platform to Aventis to enhance its existing capabilities; and purchase of an equity interest in the Company by Aventis. The companies have agreed to share the responsibility for and cost of developing, marketing and manufacturing products arising from the alliance, as well as profits in North America. Outside of North America, Aventis is responsible for developing and marketing products arising from the alliance, with a royalty obligation to the Company. Under a Technology Transfer Agreement, the Company agreed to provide Aventis with rights to its drug discovery technologies in exchange for payments of up to

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[6] Revenues and Strategic Alliances (Continued)**

\$200.0 million over a five-year period. Under an Investment Agreement, Aventis agreed to invest \$250.0 million in the Company's Common Stock. As part of this \$250.0 million equity investment, a \$150.0 million stock purchase was made in the third quarter of 2000 and a \$50.0 million stock purchase was made in January 2001. An additional \$50.0 million stock purchase is required to be made in July 2001.

**Significant Alliances Beginning in 1999**

On February 22, 1999, MPMx and Becton Dickinson formed a strategic alliance in the diagnostic field. The five-year, genomics-based research collaboration focuses on several areas of oncology. Under the alliance, MPMx has agreed to undertake a research program to identify genetic markers and related assays that may be used to develop diagnostic products for several types of cancer. Becton Dickinson has agreed to manufacture and market any products that result from the research of MPMx, and MPMx will receive a royalty based upon gross profits from any related product sales. On March 31, 1999, Becton Dickinson made a fair market value equity investment in MPMx of \$15.0 million, representing approximately an 11% voting interest in MPMx, and paid a \$3.0 million licensing fee to MPMx. On June 2, 2000 the Company acquired the outstanding Preferred and Common Stock of MPMx. Becton Dickinson received 0.8 shares of Millennium Common Stock in exchange for each MPMx share. Becton Dickinson has agreed to pay MPMx up to \$51.5 million in research funding and additional annual license fees over the term, provided the alliance continues for the full five-year term. Becton Dickinson has agreed to pay milestones and royalties to MPMx in connection with the commercialization and sale of any products developed through the alliance.

Through its merger with LeukoSite, the Company became a party to a joint venture agreement with ILEX Products, Inc. (ILEX) to form Millennium and ILEX Partners, L.P. ("M&I") for the purpose of developing and commercializing the CAMPATH® product, a monoclonal antibody for use in the treatment of chronic lymphocytic leukemia. In August 1999, M&I and Schering AG entered into a distribution and development agreement which grants Schering AG exclusive marketing and distribution rights to the CAMPATH® product in the U.S., Europe and the rest of the world except Japan and East Asia, where M&I has retained rights. In the United States, Berlex Laboratories, Inc., Schering's U.S. affiliate, and M&I will share in the profits from the sale of the CAMPATH® product. On sales made in the rest of the territory, Schering AG has agreed to pay royalties equivalent to the rate of profit sharing expected in the U.S. Under the terms of the agreement, Schering has agreed to make payments of up to \$30.0 million, of which \$20.0 million had been received at December 31, 2000, for rights to the CAMPATH® product upon the achievement of certain regulatory milestones. The joint venture currently intends to use these funds to pay for ongoing development activities. The Company accounts for its investment in the joint venture under the equity method of accounting. During the year ended December 31, 2000, the Company recognized \$5.6 million of revenue from research and development activities performed on behalf of and to be reimbursed by M&I. At December 31, 2000 and 1999, the Company had an amount receivable of \$3.8 million and \$0.3 million, respectively, included in Due from strategic alliance partners, for amounts due from M&I, for such work.

In December 2000, the Oncologic Drugs Advisory Committee (ODAC) to the FDA recommended accelerated approval of M&I's CAMPATH® product. In February 2001, M&I received a Class I complete response letter from the FDA. In the letter, the FDA indicated that the timeframe for accelerated approval has been extended for a 60-day period. M&I expects to complete ongoing discussions with the FDA on final package labeling and design of a post-marketing confirmatory study for the CAMPATH® product during this time.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[6] Revenues and Strategic Alliances (Continued)**

**Significant Alliances Beginning in 1998 and Earlier**

In September 1998, the Company entered into a strategic alliance with Bayer AG (“Bayer”). In November 1998, Bayer made an equity investment of \$96.6 million for approximately 19.8 million shares of Millennium Common Stock. The primary goal of the alliance is for the Company to supply 225 drug targets to Bayer over a period of five years. These targets will be identified as relevant for cardiovascular disease, areas of oncology not covered by Millennium’s alliance with Lilly, osteoporosis, pain, liver fibrosis, hematology and viral infections. Future anticipated payments over the full alliance term include \$219 million of ongoing research program funding, as well as a potential of up to \$116 million of success fee payments for delivery of targets. Bayer has the right to cancel the agreement after two and three years if certain minimum target delivery objectives are not met.

In October 1997, the Company entered into a technology transfer alliance through a collaborative agreement with Monsanto Company (“Monsanto”). Under this agreement, the Company granted to Monsanto exclusive rights to its technologies in the field of plant agriculture, as well as a nonexclusive license to its technologies outside the plant agriculture field. The Company has agreed to collaborate exclusively with Monsanto in the application of those technologies through the establishment of a subsidiary wholly owned by Monsanto. Monsanto agreed to pay \$118 million in up-front, licensing and technology transfer fees over the five-year term of the agreement. Monsanto may also pay the Company up to \$100 million over five years, contingent upon the achievement of mutually agreed-upon research objectives. Millennium may also receive royalty payments from the sale of products, if any, originating from the research conducted by the Monsanto subsidiary.

In July 1996, the Company entered into a strategic alliance with American Home Products (“AHP”) to discover and develop targets and assays to identify and develop small molecule drugs and vaccines for treatment and prevention of disorders of the central nervous system. In addition, this agreement provides for the license and transfer of certain technology to AHP. If certain specified research objectives are not met, AHP may terminate the agreement in September 2001. In August 1999, the Company extended the collaboration in the area of central nervous system disorders for at least an additional two years.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[7] Marketable Securities**

The following is a summary of available-for-sale securities (in thousands):

	December 31, 2000			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds:				
Due in one year or less . . . . .	\$ 73,225	\$ 397	\$ (88)	\$ 73,534
Due in one to three years . . . . .	851,862	8,805	(1,001)	859,666
Asset-backed securities				
Due in one year or less . . . . .	677	—	—	677
Due in one to three years . . . . .	305,222	1,957	(108)	307,071
U.S. government agency securities				
Due in one year or less . . . . .	2,462	13	—	2,475
Due in one to three years . . . . .	42,069	792	(3)	42,858
	\$1,275,517	\$11,964	\$(1,200)	\$1,286,281

	December 31, 1999			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds:				
Due in one year or less . . . . .	\$ 64,918	\$49	\$ (57)	\$ 64,910
Due in one to three years . . . . .	140,762	3	(734)	140,031
	\$205,680	\$52	\$(791)	\$204,941

**[8] Property and Equipment**

Property and equipment consists of the following at December 31 (in thousands):

	2000	1999
Equipment . . . . .	\$105,803	\$76,636
Capitalized software . . . . .	8,064	458
Leasehold improvements and construction in progress . . . . .	35,056	24,116
	148,923	101,210
Less accumulated depreciation and amortization . . . . .	63,120	41,667
	\$ 85,803	\$59,543

Depreciation expense was \$23.2 million, \$17.1 million, and \$13.3 million in 2000, 1999 and 1998, respectively.

**[9] Commitments**

**Lease Commitments**

The Company conducts the majority of its operations in leased facilities with leased equipment. At December 31, 2000 and 1999, respectively, the Company has capitalized leased equipment totaling

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[9] Commitments (Continued)**

\$74.3 million and \$59.2 million, with related accumulated amortization of \$39.4 million and \$29.2 million.

The Company leases its laboratory and office space under operating lease agreements with various terms and renewal options, including major facilities with lease expirations ranging from 2002 through 2020. In addition to minimum lease commitments, these lease agreements require the Company to pay its pro rata share of property taxes and building operating expenses.

On August 4, 2000 the Company entered into lease agreements relating to two buildings to be constructed for laboratory and office space. The leases commence on the earlier of September 1, 2002 or the date on which the Company commences occupancy. Both leases are for a term of seventeen years. The Company is responsible for a portion of the construction costs for both buildings. The cost to complete one of the buildings is expected to be approximately \$31.0 million and as the other building is in the design phase, construction costs are currently being estimated for that building. Rent is calculated on an escalating scale ranging from approximately \$7.6 million, per building per year, to approximately \$9.7 million, per building per year. These amounts have been excluded from the table below.

At December 31, 2000, the Company has pledged \$29.6 million of marketable securities, included in restricted cash, as collateral for letters of credit for certain leased facilities.

At December 31, 2000, future minimum commitments under leases with noncancelable terms of more than one year, excluding the August 4, 2000 leases described above, are as follows (in thousands):

	<u>Capital Leases</u>	<u>Operating Leases</u>
Year:		
2001	\$17,276	\$ 24,654
2002	15,004	24,748
2003	10,638	21,126
2004	4,873	22,880
2005	2,305	21,510
Thereafter . . . . .	—	127,250
Total . . . . .	<u>50,096</u>	<u>\$242,168</u>
Less amount representing interest . . . . .	<u>6,519</u>	
Present value of minimum lease payments . . . . .	43,577	
Less current portion of capital lease obligations . . . . .	<u>14,208</u>	
Capital lease obligations, net of current portion . . . . .	<u>\$29,369</u>	

Total rent expense was \$24.3 million, \$15.1 million and \$8.5 million in 2000, 1999 and 1998, respectively. Sublease rental income was \$0.4 million and \$0.5 million in 2000 and 1999, respectively. Interest paid under all financing and leasing arrangements during 2000, 1999 and 1998 approximated interest expense.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[9] Commitments (Continued)**

**External Collaborations**

The Company funds research efforts of various academic collaborators in connection with its research and development programs. Total future fixed commitments under these agreements approximate \$7.4 million in 2001, \$1.8 million in 2002 and \$0.2 million in 2003.

**[10] Convertible Debt**

In January 2000, the Company completed a sale, pursuant to Rule 144A of the Securities Act of 1933, of \$400.0 million of 5.5% convertible subordinated notes due January 15, 2007. The notes are convertible into Millennium Common Stock at any time prior to maturity at a price equal to \$42.07 per share, subject to adjustment, unless previously repurchased or redeemed by the Company under certain circumstances. The notes are subordinated in right of payment to all existing and future senior indebtedness of the Company. Under the terms of the notes, the Company is required to make semi-annual interest payments on the outstanding principal balance of the notes on January 15 and July 15 of each year. To date, all required interest payments have been made.

During 2000, the Company paid an aggregate of \$54.9 million in cash to certain holders of Millennium's convertible notes in order to induce the conversion of their notes into Millennium Common Stock. These cash payments were expensed during 2000. Interest accrued through the date of conversion was charged to interest expense and was paid upon conversion. These conversions resulted in the retirement of \$304.1 million of outstanding principal of Millennium convertible notes, the issuance of approximately 7.2 million shares of Millennium Common Stock, and the reclassification of deferred debt issuance costs of \$7.0 million to additional paid-in capital.

**[11] Stockholders' Equity**

**Preferred Stock**

The Company has 5,000,000 authorized shares of Preferred Stock, \$0.001 par value, issuable in one or more series, each of such series to have such rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Board of Directors.

**Common Stock**

On October 11, 2000, Millennium completed a public offering of 11,000,000 shares of its Common Stock resulting in net proceeds to the Company of approximately \$677.1 million. On October 17, 2000 the underwriters exercised their over-allotment option with respect to an additional 1,465,500 shares of Common Stock, resulting in net proceeds to the Company of an additional \$90.3 million. The Company expects to use the net proceeds of this offering for working capital and other corporate purposes including financing the Company's growth, accelerating the expansion of its technology platform, developing products, including conducting preclinical testing and clinical trials, and acquisitions of businesses, products and technologies that complement or expand the Company's business.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[11] Stockholders' Equity (Continued)**

**Common Stock Warrants**

At December 31, 2000, the Company has outstanding exercisable warrants to purchase 871,866 shares of Common Stock with a weighted-average exercise price of \$5.31 per share, which expire through 2007.

**Stock Option Plans**

The 1993 Incentive Stock Plan (the 1993 Plan) allows for the granting of incentive and nonstatutory options to purchase up to 21,600,000 shares of Common Stock. In December 1995, the Company amended the terms of outstanding option agreements to allow option holders the right to immediately exercise outstanding options, with the subsequent share issuances being subject to a repurchase option by the Company under certain conditions according to the original option vesting schedule and exercise price. At December 31, 2000, there are no longer any shares subject to the Company's repurchase option. At December 31, 2000, a total of 1,458,795 shares of Common Stock have been reserved for issuance under the 1993 Plan.

The 1996 Equity Incentive Plan (the 1996 Plan) is substantially consistent with the terms of the 1993 Plan and, as amended, provides for the granting of options to purchase 22,400,000 shares of Common Stock. At December 31, 2000, a total of 13,177,864 shares of Common Stock have been reserved for issuance under the 1996 Plan.

The 1997 Equity Incentive Plan (the 1997 Plan), as amended, provides for the granting of 16,000,000 options to purchase shares of Common Stock. The terms and conditions of the 1997 Plan are substantially consistent with those of the 1993 Plan and the 1996 Plan. At December 31, 2000, a total of 9,582,874 shares of Common Stock have been reserved for issuance under the 1997 Plan.

The 2000 Incentive Stock Plan (the 2000 Plan) allows for the granting of incentive and nonstatutory stock options, restricted stock awards and other stock-based awards, including the grant of shares based upon certain conditions, the grant of securities convertible into Common Stock and the grant of stock appreciation rights. The number of stock option shares authorized is equal to 5% of the number of shares outstanding on April 12, 2000 plus an annual increase to be made on January 1, 2001, 2002, and 2003 equal to 5% of the number of shares outstanding or a lesser amount determined by the Board of Directors. At December 31, 2000, a total of 9,136,588 shares of Common Stock have been reserved for issuance under the 2000 Plan.

The 1996 Director Option Plan (the Director Plan) provides that, upon adoption, each then-eligible nonemployee director be granted a nonstatutory option to purchase 80,000 shares of Common Stock. Thereafter, each new nonemployee director will be granted a nonstatutory option to purchase 120,000 shares of Common Stock upon election to the Board of Directors. Upon completion of the vesting of each option grant under the Director Plan, each nonemployee director will be granted a new nonstatutory option to purchase 80,000 shares of Common Stock. All options will be issued at the then fair market value of the Common Stock, vest ratably over four years and expire ten years after date of grant. At December 31, 2000, a total of 915,000 shares of Common Stock have been reserved for issuance under the Director Plan.

Under the Employee Stock Purchase Plan (the Stock Purchase Plan), eligible employees may purchase Common Stock at a price per share equal to 85% of the lower of the fair market value of the

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[11] Stockholders' Equity (Continued)**

Common Stock at the beginning or end of each offering period. Participation in the offering is limited to 10% of the employee's compensation or \$25,000 in any calendar year. The first offering period began on October 1, 1996. A total of 2,600,000 shares of Common Stock have been reserved for issuance under the Purchase Plan, as amended. At December 31, 2000, subscriptions were outstanding for an estimated 19,080 shares at \$57.72 per share.

In connection with the mergers of MBio and MPMx into the Company, MBio's 1997 Equity Incentive Plan (the MBio 1997 Plan) and MPMx's 1997 Equity Incentive Plan (the MPMx 1997 Plan) were assumed by Millennium. In December 1999, in connection with the merger of LeukoSite and the Company, Millennium assumed the LeukoSite 1993 Stock Option Plan. The Plans, as assumed, allow for the granting of incentive and nonstatutory options to purchase up to 5,293,950 shares of Millennium Common Stock. At December 31, 2000, a total of 2,451,063 shares of Common Stock have been reserved for issuance under these assumed Plans.

Options granted to employees generally vest over a four-year period. Options granted to consultants and other nonemployees generally vest over the period of service to the Company and the Company records compensation expense equal to the fair value of these options.

During 1995 and 1996, the Company granted options to purchase 6,322,728 shares of Common Stock at exercise prices below the deemed fair value for accounting purposes of the stock options at the date of grant. The Company recorded an increase to additional paid-in capital and a corresponding charge to deferred compensation in the amount of approximately \$3.5 million to recognize the aggregate difference between such deemed fair value and the exercise price. The deferred compensation was amortized over the option vesting period of four years.

During 1999, MBio granted options to purchase 76,180 shares of MBio Common Stock at exercise prices below the deemed fair value for accounting purposes of the stock options at the date of the grant. These options were converted to 59,788 options to purchase Common Stock of Millennium in connection with the merger of MBio and the Company. During 2000, MPMx granted options to purchase 93,730 shares of MPMx Common Stock at exercise prices below the deemed fair value for accounting purposes of the stock options at the date of the grant. These options were converted to 74,984 options to purchase Common Stock of Millennium in connection with the merger of MPMx and the Company. The Company recorded increases to additional paid-in capital and a corresponding charge to deferred compensation in the amount of approximately \$1.1 million and \$345,000, respectively to recognize the aggregate difference between such deemed fair value and the exercise price. The deferred compensation is being amortized over the option vesting period of four years.



**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[11] Stockholders' Equity (Continued)**

The following table presents the combined activity of the 1993 Plan, 1996 Plan, 1997 Plan, the 2000 Plan, the LeukoSite Plan, the MBio 1997 Plan, the MPMx 1997 Plan and the Director Plan for the years ended December 31, 2000, 1999 and 1998:

	2000		1999		1998	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at January 1 . . . . .	27,468,636	\$ 7.20	24,452,780	\$ 3.78	21,854,540	\$3.23
Granted . . . . .	13,611,995	47.52	13,188,624	10.93	7,589,460	4.69
Exercised . . . . .	(9,966,672)	7.23	(8,553,856)	3.79	(2,774,472)	1.46
Canceled . . . . .	(1,574,719)	17.85	(1,618,912)	4.14	(2,216,748)	4.34
Outstanding at December 31 . . . . .	<u>29,539,240</u>	<u>25.22</u>	<u>27,468,636</u>	<u>7.20</u>	<u>24,452,780</u>	<u>3.78</u>
Options exercisable at December 31 . . . .	<u>9,420,873</u>	<u>\$11.80</u>	<u>10,297,760</u>	<u>\$ 4.12</u>	<u>9,742,616</u>	<u>\$2.88</u>

The weighted-average per share fair value of options granted during 2000, 1999, and 1998 was \$31.68, \$9.10 and \$2.74, respectively.

The following table presents weighted-average price and life information about significant option groups outstanding at December 31, 2000 for the above plans:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number	Weighted-Average Remaining Contractual Life (Yrs)	Weighted-Average Exercise Price	Number	Weighted-Average Exercise Price
\$0.03 – \$4.00	3,046,955	5.96	\$ 2.28	2,155,251	\$2.08
4.13 – 4.72	4,068,464	6.82	4.44	2,581,305	4.39
4.75 – 7.53	3,060,296	7.13	5.48	1,609,028	5.34
7.57 – 9.00	3,473,777	8.27	8.26	934,991	8.17
9.09 – 30.00	3,228,660	8.80	18.74	604,343	15.81
30.40 – 43.75	1,716,827	9.17	34.98	236,194	31.77
44.00 – 44.00	4,522,582	9.20	44.00	726,085	44.00
45.00 – 48.13	3,529,520	9.24	47.16	382,394	46.78
48.56 – 72.56	2,272,867	9.37	63.03	189,610	63.68
73.03 – 73.03	619,292	9.75	73.03	1,672	73.03
	<u>29,539,240</u>			<u>9,420,873</u>	

At December 31, 2000, 37,594,050 shares of Common Stock were reserved for issuance upon exercise of stock options and warrants.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[11] Stockholders' Equity (Continued)**

**SFAS No. 123 Disclosures**

Pursuant to the requirements of SFAS No. 123, the following are the pro forma consolidated net income (loss) and consolidated net income (loss) per share for 2000, 1999, and 1998 as if the compensation cost for the stock option and stock purchase plans had been determined based on the fair value at the grant date for grants in 2000, 1999, and 1998 (in thousands, except per share amounts):

	2000		1999		1998	
	As Reported	Pro Forma	As Reported	Pro Forma	As Reported	Pro Forma
Net income (loss) attributable to common stockholders . . . . .	\$(355,287)	\$(556,676)	\$(379,904)	\$(400,972)	\$10,338	\$(6,782)
Basic net income (loss) per share . . . . .	(1.84)	(2.89)	(2.61)	(2.76)	0.09	(0.06)
Diluted net income (loss) per share . . . . .	(1.84)	(2.89)	(2.61)	(2.76)	0.08	(0.06)

The fair value of stock options and common shares issued pursuant to the Stock Option and Stock Purchase Plans at the date of grant were estimated using the Black-Scholes model with the following weighted-average assumptions:

	Stock Options			Stock Purchase Plan		
	2000	1999	1998	2000	1999	1998
Expected life (years) . . . . .	4.5	4.4	4.4	0.5	0.5	0.5
Interest rate . . . . .	6.43%	5.59%	5.36%	5.72%	4.83%	5.15%
Volatility . . . . .	.84	.67	.70	.84	.67	.70

The Company has never declared cash dividends on any of its capital stock and does not expect to do so in the foreseeable future.

The effects on 2000, 1999 and 1998 pro forma net income (loss) and net income (loss) per share of expensing the estimated fair value of stock options and common shares issued pursuant to the Stock Option and Stock Purchase Plans are not necessarily representative of the effects on reported results of operations for future years as the periods presented include only two, three and four years, respectively, of option grants and share purchases under the Company's plans.

**[12] Income Taxes**

The difference between the Company's "expected" tax provision (benefit), as computed by applying the U.S. federal corporate tax rate of 34% to income (loss) before minority interest, the

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[12] Income Taxes (Continued)**

cumulative effect of accounting change and provision for income taxes, and actual tax is reconciled in the following chart (in thousands):

	<u>2000</u>	<u>1999</u>	<u>1998</u>
Loss before minority interest and cumulative effect of accounting change . . . . .	\$(201,927)	\$(353,940)	\$(3,841)
Expected tax benefit at 34% . . . . .	\$ (68,655)	\$(120,340)	\$(1,306)
State tax benefit net of federal benefit . . . . .	110	11	(231)
Write off of purchased research and development . . . . .	—	119,171	—
Amortization of goodwill . . . . .	15,857	1,298	1,081
Change in valuation allowance for deferred tax assets allocated to tax expense . . . . .	52,315	(543)	(458)
Stock compensation expense . . . . .	280	285	788
Nondeductible expenses . . . . .	93	118	126
Income tax provision . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2000, the Company has unused net operating loss carryforwards of approximately \$720.0 million available to reduce federal taxable income expiring in 2004 through 2020 and \$660.0 million available to reduce state taxable income expiring in 2001 through 2005. The Company also has federal and state research tax credits of approximately \$32.3 million available to offset federal and state income taxes, both of which expire beginning in 2005. Due to the degree of uncertainty related to the ultimate use of the loss carryforwards and tax credits, the Company has fully reserved these tax benefits. No income tax payments were made in 2000 and 1999.

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[12] Income Taxes (Continued)**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31 are as follows (in thousands):

	<u>2000</u>	<u>1999</u>	<u>1998</u>
Net operating loss carryforwards . . . . .	\$ 287,714	\$ 70,747	\$ 6,556
Research and development tax credit carryforwards . . . . .	32,307	22,202	12,720
Capitalized research costs . . . . .	19,880	21,101	5,875
Property and other intangible assets . . . . .	12,762	5,929	3,310
Deferred revenue . . . . .	34,726	—	—
Other . . . . .	6,649	2,570	1,739
Total deferred tax assets . . . . .	<u>394,038</u>	<u>122,549</u>	<u>30,200</u>
Valuation allowance . . . . .	<u>(394,038)</u>	<u>(122,549)</u>	<u>(30,200)</u>
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance increased by \$271.5 million during 2000 due primarily to the increase in research and development tax credits, net operating loss carryforwards related to the exercise of stock options and the cumulative effect of accounting change. The valuation allowance increased by \$92.3 million during 1999 due primarily to the increase in research and development tax credits, net operating loss carryforwards and the addition of various deferred tax assets related to the LeukoSite merger offset by the utilization of net operating loss carryforwards. The deferred tax assets acquired from LeukoSite and ChemGenics are subject to review and possible adjustments by the Internal Revenue Service and may be limited due to the change in ownership provisions of the Internal Revenue Code.

Any subsequently recognized tax benefits relating to the valuation allowance for deferred tax assets as of December 31, 2000 would be allocated as follows (in thousands):

Reported in the statement of operations . . . . .	\$133,580
Reported as a decrease to goodwill . . . . .	57,285
Reported in additional paid-in capital . . . . .	<u>203,173</u>
	<u>\$394,038</u>

**[13] Subsequent Events (unaudited)**

On January 2001, Aventis made a \$50.0 million purchase of Millennium Common Stock pursuant to the Investment Agreement between the Company and Aventis.

In February 2001, the Company entered into an Agreement for Lease, relating to a building to be constructed for laboratory and office space in Cambridge, England. The lease is expected to have a 20-year term and to commence in 2003. The Company is responsible for a portion of the construction costs, which it estimates to be approximately \$21.0 million. Rent is expected to be approximately \$2.4 million per year and is subject to market adjustments at the end of the 5<sup>th</sup>, 10<sup>th</sup> and 15<sup>th</sup> years.

In February 2001, M&I received a Class I complete response letter from the FDA relating to the CAMPATH® product. In the letter, the FDA indicated that the timeframe for accelerated approval has been extended for a 60-day period. M&I expects to complete ongoing discussions with the FDA on

**Millennium Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2000**

**[13] Subsequent Events (unaudited) (Continued)**

final package labeling and design of a post-marketing confirmatory study for the CAMPATH® product during this time.

In March 2001, the Company entered into a strategic alliance with Abbott Laboratories. This alliance is for a five-year term, and is primarily for collaborative research and development in the area of metabolic diseases. The Company and Abbott have agreed to share equally the cost of developing, manufacturing and marketing products on a worldwide basis. This arrangement with Abbott also includes a technology exchange and development agreement and an equity investment by Abbott, under which the Company is eligible to receive up to \$250 million. As part of this \$250.0 million equity investment, Abbott has agreed to make an initial investment of \$50.0 million in April 2001 and additional investments totalling \$200 million in seven quarterly installments from later in 2001 through 2003.

**[14] Quarterly Financial Information (unaudited)**

The quarterly information for the four quarters of 2000 reflects the quarters as previously reported prior to the adoption of SAB 101, and as restated for the retroactive adoption of SAB 101 to January 1, 2000, as noted in the column headings. The 1999 quarterly information has not been restated for the adoption of SAB 101.

	First Quarter Ended March 31, 2000		Second Quarter Ended June 30, 2000		Third Quarter Ended September 30, 2000		Fourth Quarter Ended December 31, 2000	
	As Previously Reported	As Restated	As Previously Reported	As Restated	As Previously Reported	As Restated	As Previously Reported	As Restated
Statement of Operations Data:								
Revenue under strategic alliances . . . . .	\$ 46,773	\$ 47,236	\$ 46,873	\$ 46,473	\$ 49,847	\$ 43,874	\$ 69,697	\$ 58,686
Costs and expenses:								
Research and development . . . . .	60,100	60,100	62,011	62,011	68,783	68,783	77,846	77,846
General and administrative . . . . .	10,823	10,823	11,057	11,057	12,439	12,439	14,996	14,996
Amortization of intangible assets . . . . .	11,970	11,970	12,161	12,161	14,480	14,480	16,512	16,512
Total costs and expenses . . . . .	82,893	82,893	85,229	85,229	95,702	95,702	109,354	109,354
Loss from operations . . . . .	(36,120)	(35,657)	(38,356)	(38,756)	(45,855)	(51,828)	(39,657)	(50,668)
Other income, net . . . . .	2,888	2,888	2,775	2,775	5,472	5,472	18,699	18,699
Debt conversion expense . . . . .	—	—	—	—	(49,332)	(49,332)	(5,520)	(5,520)
Net loss . . . . .	(33,232)	(32,769)	(35,581)	(35,981)	(89,715)	(95,688)	(26,478)	(37,489)
Deemed preferred stock dividend . . . . .	—	—	(45,668)	(45,668)	—	—	—	—
Net loss attributable to common stockholders . . . . .	<u>\$(33,232)</u>	<u>\$(32,769)</u>	<u>\$(81,249)</u>	<u>\$(81,649)</u>	<u>\$(89,715)</u>	<u>\$(95,688)</u>	<u>\$(26,478)</u>	<u>\$(37,489)</u>
<b>Amounts per common share:</b>								
Basic and diluted net loss per share . . . . .	\$ (0.18)	\$ (0.18)	\$ (0.44)	\$ (0.44)	\$ (0.46)	\$ (0.49)	\$ (0.13)	\$ (0.18)
Weighted average shares, basic and diluted . . . . .	180,890	180,890	184,440	184,440	193,570	193,570	211,786	211,786
<b>Statement of Operations Data:</b>								
Revenue under strategic alliances . . . . .	\$ 40,992	\$ 47,273	\$ 47,316	\$ 40,316	\$ 40,316	\$ 40,316	\$ 55,098	\$ 55,098
Costs and expenses:								
Research and development . . . . .	35,433	35,433	39,484	39,484	38,359	38,359	46,601	46,601
General and administrative . . . . .	7,126	7,126	8,502	8,502	8,279	8,279	8,989	8,989
Acquired in-process R&D . . . . .	676	676	675	675	676	676	350,503	350,503
Amortization of intangible assets . . . . .	—	—	—	—	—	—	1,789	1,789
Total costs and expenses . . . . .	43,235	43,235	48,661	48,661	47,314	47,314	407,882	407,882
Loss from operations . . . . .	(2,243)	(2,243)	(1,388)	(1,388)	(6,998)	(6,998)	(352,784)	(352,784)
Other income, net . . . . .	4,315	4,315	2,392	2,392	2,529	2,529	2,217	2,217
Net income (loss) . . . . .	<u>\$ 2,072</u>	<u>\$ 2,072</u>	<u>\$ 1,004</u>	<u>\$ (4,469)</u>	<u>\$ (4,469)</u>	<u>\$ (4,469)</u>	<u>\$(350,567)</u>	<u>\$(350,567)</u>
Basic net income (loss) per share . . . . .	\$ 0.01	\$ 0.01	\$ 0.01	\$ (0.03)	\$ (0.03)	\$ (0.03)	\$ (2.31)	\$ (2.31)
Weighted average shares, basic . . . . .	141,260	141,260	143,276	143,276	145,480	145,480	151,532	151,532
Diluted net income (loss) per share . . . . .	\$ 0.01	\$ 0.01	\$ 0.01	\$ (0.03)	\$ (0.03)	\$ (0.03)	\$ (2.31)	\$ (2.31)
Weighted average shares, diluted . . . . .	152,774	152,774	153,964	153,964	145,480	145,480	151,532	151,532

**Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

During the Company's two most recent fiscal years there have been no disagreements with our independent accountants on accounting and financial disclosure matters.

**PART III**

**Item 10. DIRECTORS AND EXECUTIVE OFFICERS**

Except as set forth below, the information required by this item is incorporated by reference from the information under the captions "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the Company's 2001 Annual Meeting of Stockholders to be held on May 10, 2001 (the "Proxy Statement").

Certain required information about Executive Officers of the Company is contained in Part I of this Annual Report on Form 10-K under the heading "Executive Officers of the Company."

**Item 11. EXECUTIVE COMPENSATION**

The information required regarding executive compensation is incorporated by reference from the information under the captions "Director Compensation," "Compensation of Executive Officers," "Compensation Committee Report on Executive Compensation" and "Compensation Committee Interlocks and Insider Participation" contained in the Proxy Statement.

**Item 12. STOCK OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The information required by this item is incorporated by reference from the information under the caption "Ownership of Millennium's Common Stock" contained in the Proxy Statement.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

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

**PART IV**

**Item 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K**

(a) The following documents are included as part of this Annual Report on Form 10-K.

1. Financial Statements:

	<u>Page number in this Report</u>
Report of Independent Auditors on Financial Statements . . . . .	44
Consolidated Balance Sheets at December 31, 2000 and 1999 . . . . .	45
Consolidated Statements of Operations for the years ended December 31, 2000, 1999, and 1998 . . . . .	46
Consolidated Statements of Cash Flows for the years ended December 31, 2000, 1999, and 1998 . . . . .	47
Statements of Stockholders' Equity for the years ended December 31, 2000, 1999, and 1998 . . . . .	48
Notes to Financial Statements . . . . .	49

2. All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.
  3. The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as a part of this Annual Report on Form 10-K.
- (b) The following Current Reports on Form 8-K were filed with the Securities and Exchange Commission by the Company since October 1, 2000:
1. A Current Report on Form 8-K was filed on October 2, 2000 to report, pursuant to Item 5, that (i) the Company had issued a press release announcing a public offering of common stock and (ii) that its Board of Directors approved the acceleration of the dividend distribution date for its previously announced two-for-one stock split to October 4, 2001.
  2. A Current Report on Form 8-K was filed on October 6, 2000 to file, pursuant to Item 5, an underwriting agreement for the Company's October 2000 public offering of common stock.
  3. A Current Report on Form 8-K was filed on January 24, 2001 to report, pursuant to Item 5, that the Company adopted Staff Accounting Bulletin 101 "Revenue Recognition in Financial Statements" in the fourth quarter of 2000 and recorded a cumulative effect of change in accounting principle related to contract revenues recognized in prior periods resulting in a one-time, non-cash charge of \$107.7 million for the year ended December 31, 2000.
  4. A Current Report on Form 8-K was filed on March 12, 2001 to report, pursuant to Item 5, that the Company had issued a press release announcing that the Company and Abbott Laboratories had entered into a strategic alliance for collaborative research and development in the area of metabolic diseases, including an equity investment by Abbott of up to \$250 million over the first two years of the collaboration.

*The following are trademarks of the Company, some of which are mentioned in this Annual Report on Form 10-K: "Changing the Practice of Medicine"<sup>SM</sup>, Chemoprediction<sup>TM</sup>, Cytomed<sup>®</sup>, DGx<sup>®</sup>, Diagnostics<sup>®</sup>, Expression Explorer<sup>®</sup>, G2P<sup>TM</sup>, "Gene to Patient"<sup>TM</sup>, the Millennium M logo and design (registered), MBio<sup>TM</sup>, Melastatin<sup>®</sup>, Millennium<sup>®</sup>, Millennium Biotherapeutics<sup>®</sup>, Millennium Information<sup>TM</sup>, Millennium Pharmaceuticals<sup>®</sup>, Millennium Predictive Medicine<sup>®</sup>, MPMx<sup>®</sup>, Pharmacoinformatics<sup>TM</sup>, Protein Explorer<sup>TM</sup>, RADE<sup>TM</sup>, Sequence Explorer<sup>®</sup>, SmartChip<sup>®</sup>, and "Transcending the Limits of Medicine"<sup>SM</sup>. CAMPATH<sup>®</sup> is a registered trademark, and MABCAMPATH<sup>TM</sup> is a trademark, of Millennium & ILEX Partners. Other trademarks used in this Annual Report on Form 10-K are the property of their respective owners.*





## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
<b><u>Articles of Incorporation and By-laws</u></b>	
3.1	(2)(15) Amended and Restated Certificate of Incorporation of the Company, as amended.
3.2	(2)(14)(17) Amended and Restated Bylaws of the Company, as amended.
<b><u>Instruments defining the rights of security holders, including indentures</u></b>	
4.1	(1) Specimen Certificate for shares of Common Stock, \$.001 par value, of the Company.
4.2	(18) Indenture, dated as of January 20, 2000, between the Company and State Street Bank and Trust Company, as Trustee (including the form of debenture).
<b><u>Material Contracts</u></b>	
10.1	(4)(5)(18) Form of Master Equipment Lease Financing Agreement, dated September 19, 1996 by and between the Company and GE Capital Corporation, as amended.
10.2	* Addendum No. 4 dated February 28, 2001 to Master Lease Agreement dated as of September 19, 1996.
10.3	(1)(18)(9) Lease Agreement dated August 26, 1993, as amended, by and between the Company and the Massachusetts Institute of Technology, as amended, for 640 Memorial Drive, Cambridge, MA.
10.4	* Lease Extension Agreement dated December 1, 2000 by and between the Company and the Massachusetts Institute of Technology for 640 Memorial Drive, Cambridge, MA.
10.5	(7)(18) Lease dated November 17, 1997 by and between the Company and FC 45/75 Sidney, Inc., as amended, for 45 and 75 Sidney Street, Cambridge, MA.
10.6	(17) Lease Agreement dated August 4, 2000 by and between the Company and Forest City Enterprises, Inc. for 35 Landsdowne Street, Cambridge, MA.
10.7	(17) Lease Agreement dated August 4, 2000 by and between the Company and Forest City Enterprises, Inc. for 40 Landsdowne Street, Cambridge, MA.
10.8	* Agreement for Lease dated February 9, 2001 among Granta Park Limited, MEPC Limited, Millennium Pharmaceuticals Limited and the Company (including the form of lease).
10.9	+(3) CNS Research, Collaboration and License Agreement effective as of August 1, 1996 by and between American Home Products Corporation and the Company.
10.10	+(5) Sponsored Research Agreement by and among Whitehead Institute for Biomedical Research, Affymetrix, Inc., Bristol-Myers Squibb Company and the Company dated April 28, 1997.
10.11	+(5) Consortium Member Agreement by and among Affymetrix, Inc., Bristol-Myers Squibb Company and the Company dated April 28, 1997.
10.12	+(6) Agreement dated October 27, 1997 by and among the Company, Monsanto Company and Cereon Genomics Inc. (formerly Monsanto Agricultural Genomics II LLC).
10.13	+(9)(17) Agreement dated September 22, 1998 by and between the Company and Bayer AG, as amended.

Exhibit No.	Description
10.14	+* Amendment No. 4 dated December 1, 2000 to the Agreement dated September 22, 1998 by and between the Company and Bayer AG.
10.15	(9) Investment Agreement dated September 22, 1998 by and between Bayer AG and the Company.
10.16	(9) Registration Rights Agreement dated November 10, 1998 by and between Bayer AG and the Company.
10.17	+(10) Collaboration and License Agreement dated February 21, 1999 by and between the Company (as successor to Millennium Predictive Medicine, Inc.) and Becton, Dickinson and Company.
10.18	+* First Amendment dated as of November 17, 2000 to the Collaboration and License Agreement dated February 21, 1999 by and between the Company (as successor to Millennium Predictive Medicine, Inc.) and Becton, Dickinson and Company.
10.19	+* Second Amendment dated as of December 20, 2000 to the Collaboration and License Agreement dated February 21, 1999 by and between the Company (as successor to Millennium Predictive Medicine, Inc.) and Becton, Dickinson and Company.
10.20	+(18) Supply Agreement dated as of June 4, 1999 between Millennium & ILEX Partners, L.P. (formerly L&I Partners, L.P.) and Boehringer Ingelheim Pharma KG.
10.21	+(11) License Agreement between the Company (as successor to LeukoSite, Inc.) and British Technology Group Limited dated March 31, 1997.
10.22	* Supplemental Agreement dated May 19, 1998 between British Technology Group Limited and the Company (as successor to LeukoSite, Inc.) to the License Agreement between the Company (as successor to LeukoSite, Inc.) and British Technology Group Limited dated March 31, 1997.
10.23	+* Deed of Variation dated May 19, 1998 between British Technology Group Limited and the Company (as successor to LeukoSite, Inc.) to the License Agreement between the Company (as successor to LeukoSite, Inc.) and British Technology Group Limited dated March 31, 1997.
10.24	+* Further Deed of Variation dated August 23, 1999 between BTG International Limited and the Company (as successor to LeukoSite, Inc.) to the License Agreement between the Company (as successor to LeukoSite, Inc.) and British Technology Group Limited dated March 31, 1997.
10.25	+(11) License Agreement, dated May 2, 1997, between Millennium & ILEX Partners, L.P. (formerly L&I Partners, L.P.) and the Company (as successor to LeukoSite, Inc.).
10.26	* First Amended and Restated Agreement of Limited Partnership of Millennium & ILEX Partners L.P. (formerly L&I Partners, L.P.).
10.27	+(12) Development Collaboration and License Agreement, dated as of December 18, 1997, between the Company (as successor to LeukoSite, Inc.) and Genentech, Inc.

<u>Exhibit No.</u>	<u>Description</u>
10.28	+(13) Distribution and Development Agreement dated August 24, 1999 between Millennium & ILEX Partners, L.P. (formerly L&I Partners, L.P.) and Schering AG.
10.29	+* Amendment No. 1 dated December 19, 2000 to Distribution and Development Agreement dated August 24, 1999 between Millennium & ILEX Partners, L.P. (formerly L&I Partners, L.P.) and Schering AG.
10.30	(18) Registration Rights Agreement dated January 20, 2000 between the Company and Goldman, Sachs & Co., ING Barings LLC, FleetBoston Robertson Stephens Inc., and Credit Suisse First Boston Corporation.
10.31	+(16) Collaboration and License Agreement dated June 22, 2000 by and between the Company and Aventis Pharmaceuticals, Inc.
10.32	+(16) Technology Development Agreement dated June 22, 2000 by and between the Company and Aventis Pharmaceuticals, Inc.
10.33	+(16) Technology Transfer Agreement dated June 22, 2000 by and between the Company and Aventis Pharmaceuticals, Inc.
10.34	(16) Registration Rights Agreement dated June 22, 2000 by and among the Company and Aventis Pharmaceuticals, Inc.
10.35	(16) Investment Agreement dated June 22, 2000 by and between the Company and Aventis Pharmaceuticals, Inc.

**Material contracts—management contracts and compensatory plans**

10.36	(1)# 1996 Director Option Plan.
10.37	(1)# Agreement dated as of April 21, 1993, by and between the Company and Raju Kucherlapati.
10.38	(1)# Letter Agreement dated April 14, 1994 by and between the Company and Steven H. Holtzman.
10.39	(18)# Form of Employment Offer Letter entered into with certain executive officers of the Company, together with a schedule of parties thereto.
10.40	*# Form of Promissory Notes made in favor of the Company by certain executive officers of the Company, together with a schedule of parties thereto.
10.41	*# Form of Stock Restriction Agreement entered into with certain executive officers of the Company, together with a schedule of parties thereto.
10.42	*# Executive Employment Agreement with Paul R. Hamelin dated September 29, 2000.
10.43	*# Promissory Note dated January 3, 2001 made in favor of the Company by Paul R. Hamelin.
21	* Subsidiaries of the Company.
23.1	* Consent of Ernst & Young LLP, Independent Auditors.

(1) Incorporated herein by reference to the Company's Registration Statement on Form S-1, as amended (File No. 333-2490).

(2) Incorporated herein by reference to the Company's 10-Q for the quarter ending March 31, 1996.

(3) Incorporated herein by reference to the Company's 10-Q for the quarter ending June 30, 1996.

- (4) Incorporated herein by reference to the Company's 10-Q for the quarter ending September 30, 1996.
  - (5) Incorporated herein by reference to the Company's 10-Q for the quarter ending June 30, 1997.
  - (6) Incorporated hereby by reference to the Company's Amendment No. 1 to Current Report on Form 8-K, filed with the SEC on January 30, 1998.
  - (7) Incorporated herein by reference to the Company's 10-K for the fiscal year ending December 31, 1997.
  - (8) Incorporated herein by reference to the Company's 10-Q for the quarter ending September 30, 1998.
  - (9) Incorporated herein by reference to the Company's 10-K for the fiscal year ending December 31, 1998.
  - (10) Incorporated herein by reference to the Company's 10-Q for the quarter ending June 30, 1999.
  - (11) Incorporated by reference to LeukoSite's Registration Statement on Form S-1 (No. 333-30213).
  - (12) Incorporated by reference to LeukoSite's Current Report on Form 8-K dated January 26, 1998.
  - (13) Incorporated by reference to LeukoSite's Current Report on Form 8-K dated August 24, 1999.
  - (14) Incorporated herein by reference to the Company's 10-Q for the quarter ending March 31, 2000.
  - (15) Incorporated herein by reference to the Company's Currant Report on Form 8-K dated April 12, 2000.
  - (16) Incorporated herein by reference to the Company's 10-Q for the quarter ending June 30, 2000.
  - (17) Incorporated herein by reference to the Company's 10-Q for the quarter ending September 30, 2000.
  - (18) Incorporated herein by reference to the Company's 10-K for the fiscal year ending December 31, 1999.
- # Management contract or compensatory plan or arrangement filed as an exhibit to this Form pursuant to Items 14(a) and 14(c) of Form 10-K.
- \* Filed herewith.
- + Confidential treatment requested as to certain portions.



## Board of Directors

### **Mark J. Levin**

Chairman, President and Chief Executive Officer  
Millennium Pharmaceuticals, Inc.

### **Eugene Cordes, Ph.D.**

Professor of Pharmacy and Adjunct Professor of Chemistry  
University of Michigan, Ann Arbor

### **A. Grant Heidrich, III**

General Partner  
Mayfield

### **Raju Kucherlapati, Ph.D.**

Professor and Chairman, College of Molecular Genetics  
Albert Einstein College of Medicine

### **Eric S. Lander, Ph.D.**

Director of the Whitehead/MIT Center for Genome Research

### **Edward D. Miller, Jr., M.D.**

Dean of Johns Hopkins University School of Medicine  
CEO, Johns Hopkins Medicine

### **Norman C. Selby**

Private investor

### **Kenneth E. Weg**

Principal  
Clearview Projects

## Corporate Officers

### **Mark J. Levin**

Chairman, President and Chief Executive Officer

### **Kenneth J. Conway**

President, Millennium Predictive Medicine, Inc.

### **John B. Douglas III**

Senior Vice President, General Counsel and Secretary

### **Paul J. Hamelin**

Senior Vice President, Commercial Operations

### **Steven H. Holtzman**

Chief Business Officer

### **John Maraganore, Ph.D.**

Senior Vice President, Strategic Product Development

### **Linda K. Pine**

Senior Vice President, Human Resources

### **Kevin P. Starr**

Senior Vice President and Chief Financial Officer

### **Robert I. Tepper, M.D.**

Senior Vice President and Chief Scientific Officer

### **Susan J. Ward, Ph.D.**

Senior Vice President, Strategy Leadership

## Corporate Headquarters

Millennium Pharmaceuticals, Inc.  
75 Sidney Street  
Cambridge, Massachusetts 02139

## Internet Address

[www.millennium.com](http://www.millennium.com)

## Auditors

Ernst & Young LLP  
Boston, Massachusetts

## Common Stock

Listed on NASDAQ: MLNM

## Annual Meeting

May 10, 2001  
10:00am EDT  
Hale and Dorr LLP  
60 State Street  
Boston, Massachusetts 02109

## Transfer Agent & Registrar


State Street Bank and Trust Company  
c/o EquiServe  
150 Royall Street  
Canton, Massachusetts 02021  
[www.equiserve.com](http://www.equiserve.com)

## SEC Form 10-K

A copy of the Company's annual report to the Securities and Exchange Commission on Form 10-K is available without charge upon written request to Investor Relations, Millennium Pharmaceuticals, Inc., 75 Sidney Street, Cambridge, Massachusetts 02139.

## Stockholder Inquiries

Inquiries related to stock transfer or lost certificates should be directed to the Transfer Agent at 877.282.1168 or at [www.equiserve.com](http://www.equiserve.com). General information regarding the Company can be obtained by contacting Millennium's investor relations department at 617.679.7000 or through our web site at [www.millennium.com](http://www.millennium.com). Recent news releases can also be obtained by contacting Millennium's auto-mated fax-on-demand line at 800.758.5804 and entering the PIN number 114562.



Transcending  
the Limits of Medicine<sup>SM</sup>



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