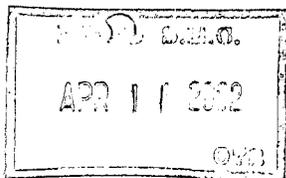


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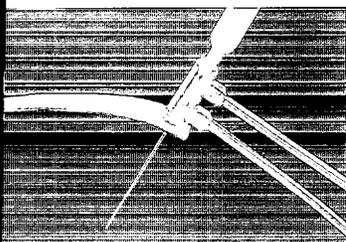
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FINANCIAL



# Cytoc Corporation

The Next Generation of Healthcare



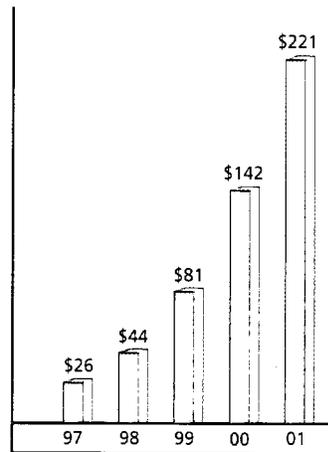


# About Cytyc

Cytyc Corporation develops, manufactures, and markets products for medical diagnostic applications primarily focused on women's health. Cytyc's ThinPrep® System is widely used for cervical cancer screening and serves as a platform for the Company's expansion into breast cancer risk assessment with the FirstCytel™ Ductal Lavage. The ThinPrep System consists of the ThinPrep® 2000 Processor, ThinPrep® 3000 Processor, and related reagents, filters, and other supplies. Cytyc is traded on The Nasdaq Stock Market under the symbol CYTC and is a part of the S&P Midcap 400 Index and The Nasdaq-100 Index.

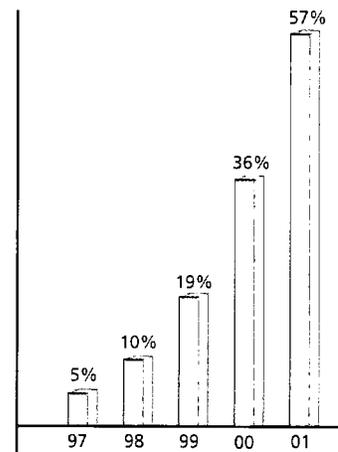
## 2001 Highlights

**Worldwide Revenues**  
(in millions)



56 percent increase  
in revenues in 2001

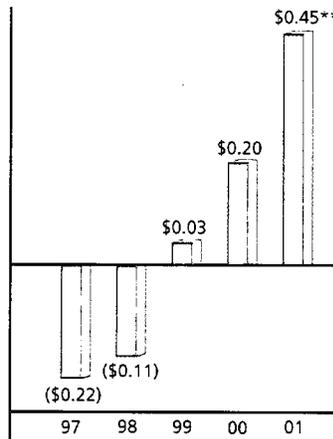
**U.S. Market Share**



58 percent increase  
in market share in 2001

**Earnings Per Share\***

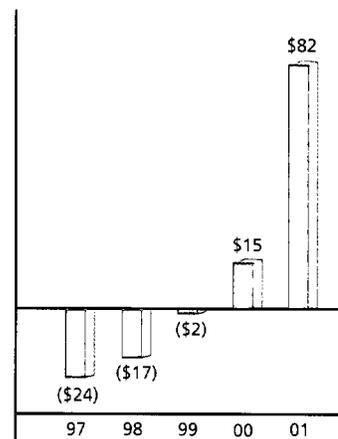
(Pro forma, fully taxed, fully diluted)



\*Earnings per share reflect a two-for-one stock split effective January 28, 2000, and a three-for-one stock split effective March 2, 2001.

**Cash Flow\***

(in millions)



\*Net cash provided by operating activities less purchases of property and equipment

\*\*Pro forma fully taxed, fully diluted EPS for 2001 excludes a one-time charge of \$56 million for in process research and development related to Pro-Duct Health acquisition and \$3.1 million gain on litigation settlement.

## Selected Financial Data

(Dollars in thousands, except per share data)

Statement of Operations Data	Year Ended December 31,				
	2001	2000	1999	1998	1997
Sales	\$220,993	\$142,065	\$81,100	\$ 44,264	\$ 26,347
Gross profit	180,825	117,500	65,285	33,053	18,341
Operating expenses*	151,123	83,205	64,154	52,123	45,555
Operating income (loss)	29,702	34,295	1,131	(19,070)	(27,214)
Interest and other income**	8,006	4,721	4,639	7,341	5,142
Provision for income taxes	25,073	853	130	—	—
Net income (loss)	\$ 12,635	\$ 38,163	\$ 5,640	\$ (11,729)	\$ (22,072)
Basic net income (loss) per share	\$ 0.11	\$ 0.34	\$ 0.05	\$ (0.11)	\$ (0.22)
Diluted net income (loss) per share	\$ 0.10	\$ 0.32	\$ 0.05	\$ (0.11)	\$ (0.22)
<b>Balance Sheet Data</b>					
Cash, cash equivalents and short term investments	\$153,242	\$ 88,845	\$70,368	\$ 69,908	\$ 85,402
Property and equipment, net	26,662	21,363	10,660	8,825	5,851
Total assets	386,760	170,886	112,328	97,737	108,377
Total liabilities	36,452	23,840	17,337	11,930	12,190
Stockholders' equity	\$350,308	\$147,046	\$94,991	\$ 85,807	\$ 96,187

\* For 2001 includes a one-time charge of \$56 million for in process research and development related to Pro-Duct Health acquisition.

\*\* For 2001 includes \$3.1 million gain on litigation settlement.

Forward-looking statements in this report are made pursuant to the provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that statements in this report which are not strictly historical statements, including, without limitation, statements regarding management's expectations for future growth and operations, constitute forward-looking statements which involve risks and uncertainties which could cause actual results to differ, including, without limitation, risks associated with the Company's dependence on a single product, uncertainty of product development efforts, risks associated with the FDA regulatory approval process, uncertainty of market acceptance and additional cost, dependence on proprietary technology, dependence on timely and adequate levels of third-party reimbursement, dependence on key personnel, management of growth, risks associated with the consummation and integration of the Digene acquisition and the integration and commercialization of the Pro-Duct Health ductal lavage business, limited marketing and sales experience, and limited number of customers and lengthy sales cycle, as well as risks of downturns in economic conditions generally, and in the healthcare industry specifically, risks associated with competition and competitive pricing pressures, potential liabilities and costs associated with litigation, and other risks detailed in the Company's filings with the Securities and Exchange Commission, included in its 2001 Form 10-K filed with the Commission.



## To Our Shareholders

Building on our success in women's health

We are extremely pleased with the performance of the Company for the past year and at the same time excited about our future prospects. The year 2001 was a period of strong growth for the Company, as revenues increased 56 percent to \$221 million and pro forma net income increased to \$54 million. We finished the year with \$153 million in cash and investments and no debt, providing a solid foundation to fund additional growth initiatives.

Our estimated U.S. market share in the last quarter of 2001 was approximately 57 percent of all cervical cancer screening tests; up from 36 percent at the end of 2000, representing a one-year gain of 21 percentage points. We continued to make progress during the year in three main areas of our marketing focus: the laboratory, physician usage, and health insurance coverage.

We also achieved a number of significant milestones in 2001. In August 2001, the U.S. Food and Drug Administration (FDA) approved our Premarket Approval (PMA) Supplement allowing inclusion of data describing the detection of High-Grade Squamous Intraepithelial Lesions (HSIL) with the ThinPrep® Pap Test™ Package Insert. The data, from a 30,000-patient, multi-site clinical outcomes trial, demonstrated a 59 percent increase in the detection of high-grade lesions. In September, the U.S. Army awarded us a sole source contract implementing the ThinPrep Pap Test as the standard of care for its cervical cancer screening centers worldwide.

The PMA supplement to allow testing for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG) was submitted to the FDA at the beginning of December, and we expect approval in the first half of this year. The PMA application for the ThinPrep® Imaging System™ was submitted to the FDA at the beginning

of January 2002, and we expect the product to be available commercially in the U.S. later this year and internationally in the third quarter.

As a result of our domestic success, we are increasing our marketing and sales efforts in Europe. Approximately 60 million Pap tests are performed outside the U.S., and Cytoc has recently focused sales and marketing efforts in Europe, where approximately 36 million tests are performed each year.

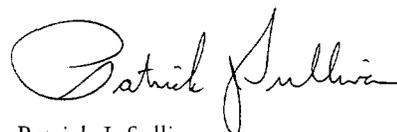
Another major milestone this year was our acquisition of Pro-Duct Health, Inc., a privately held company that has developed an innovative, FDA-approved ductal lavage device designed to enhance the evaluation of risk for breast cancer. We have made significant progress integrating this exciting new product into our organization and have initiated efforts to commercialize FirstCytoc Ductal Lavage for breast cancer risk assessment.

In November 2001, the results of the pivotal trial of ductal lavage in 507 high-risk patients conducted at 19 centers were published in the *Journal of the National Cancer Institute*. These results demonstrated the ability of the ductal lavage procedure to significantly improve the clinician's ability to collect and evaluate epithelial cells from the lining of breast milk ducts, where virtually all breast cancers originate. These data provide dramatic evidence that the ductal lavage procedure will play a pivotal role in the ongoing assessment of risk for the more than 5 million women in the U.S. who are at high risk for breast cancer. In addition, a key article by some of the leading breast cancer risk management authorities was published in the journal *Cancer* in January 2002. The article describes appropriate treatment choices and follow-up of ductal lavage results in high-risk patients.

By early January of this year, the Cytoc 20-person ductal lavage sales force was trained and began calling on breast surgeons and radiologists to promote the use of ductal lavage as a key element in the risk assessment process. We believe one critical challenge we face in expanding the use of the ductal lavage procedure is insurance reimbursement. In this regard, we were pleased to announce that Empire Blue Cross, Blue Shield, the largest provider of health insurance in the State of New York, announced that it will provide reimbursement for ductal lavage for its high-risk breast cancer subscribers.

On February 19, 2002, we signed a definitive agreement to acquire Digene Corporation in a stock and cash exchange offer. We believe this is a strong strategic fit for both companies, each leaders in our respective fields. We believe Cytoc's ThinPrep Pap Test is becoming the standard for cervical cancer screening and Digene's Hybrid Capture® 2 HPV Test is the clear standard for the detection of human papillomavirus (HPV), which is the cause of greater than 99 percent of cervical cancer cases. In addition, we believe the combined platform of Hybrid Capture 2 technology based on Digene's substantial portfolio of intellectual property, together with the ThinPrep Pap Test sample collection process, provides additional opportunities for molecular testing of a variety of sexually transmitted diseases. We believe the transaction furthers Cytoc's mission to become the leading developer and manufacturer of products for the diagnosis of women's cancers and infectious diseases.

In summary, we believe our exciting growth initiatives, combined with the organization we have in place, position Cytoc Corporation to maintain our formidable record of consistent growth and to fulfill our mission to significantly improve women's health.



Patrick J. Sullivan

Vice Chairman, Chairman-Elect, and Chief Executive Officer

## At the Laboratory

### Dispersion

The vial is placed into the ThinPrep 2000 or ThinPrep 3000 Processor. The TransCyt® Filter rotates within the cell suspension, gently separating cells from blood, mucus, and inflammation without affecting cell morphology.



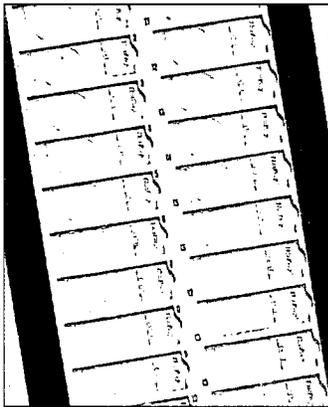
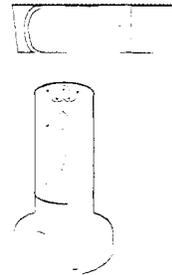
### Cell Collection

A vacuum is then applied to the TransCyt Filter, which collects cells onto the exterior surface of the filter membrane. The ThinPrep Processor automatically calculates the number of cells collected.

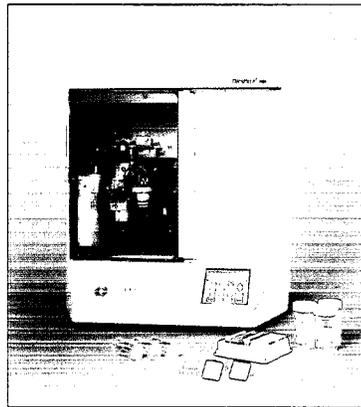


### Slide Preparation

The ThinPrep Processor inverts the filter against a microscope slide and reverses the air pressure, distributing a thin layer of cells in a defined circular area. If needed, additional slides can be produced from the original sample.



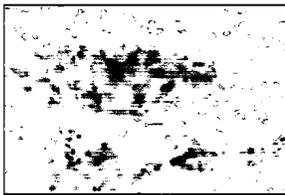
ThinPrep-processed slides are uniform.



At the laboratory, the collection vial containing the patient's sample is placed into the ThinPrep Processor.

## Results

### ThinPrep Pap Test



#### Conventional Pap Smear Slide

Blood, mucus, and inflammation can obscure cervical cells, making a diagnosis difficult.

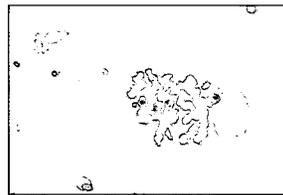


#### ThinPrep Pap Test

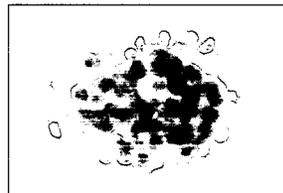
Through processing, obscuring elements are removed. The result significantly improves diagnostic review.

(40x magnification)

### FirstCyt® Ductal Lavage



Ductal lavage displaying mild atypia.



Ductal lavage displaying marked atypia.

(60x magnification)

# The ThinPrep® System: How It Works

Approved by the FDA in 1996, the ThinPrep System is the only replacement to the conventional Pap test that has received FDA clearance stating that the product is significantly more effective than the conventional Pap test for the detection of Low-Grade Squamous Intraepithelial (LSIL) and more severe lesions in a variety of patient populations. Data from a recent clinical outcomes trial, where ThinPrep specimens were collected prospectively and compared against an historical control cohort,

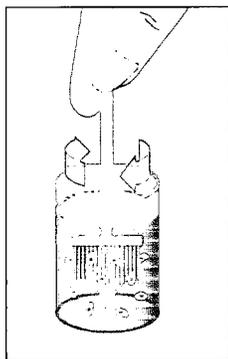
indicated a 59.7 percent increase in the detection of High-Grade Squamous Intraepithelial (HSIL) and more severe lesions.

The ThinPrep System is the foundation for the ThinPrep Pap Test and the FirstCyte Ductal Lavage. After cell collection for the ThinPrep Pap Test and the FirstCyte Ductal Lavage, test samples are sent to the laboratory for processing using the ThinPrep System.

## At the Physician's Office



### ThinPrep® Pap Test™

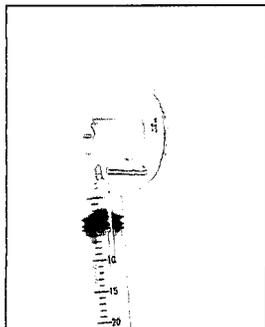


#### Sample Collection

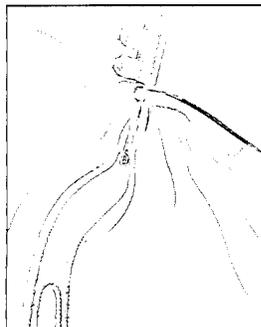
Cervical cells are rinsed from the collection device into a vial filled with PreservCyt® Solution, then sent to a laboratory equipped with a ThinPrep 2000 or ThinPrep 3000 Processor.



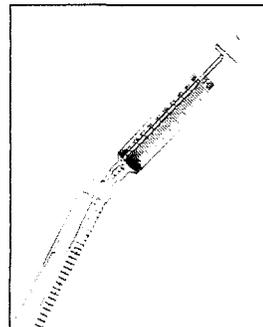
### FirstCyte™ Ductal Lavage



Ducts containing nipple aspirate fluid are identified.



Ducts with fluid are lavaged with a patented microcatheter.



Sample is placed in a proprietary solution and sent to the laboratory.

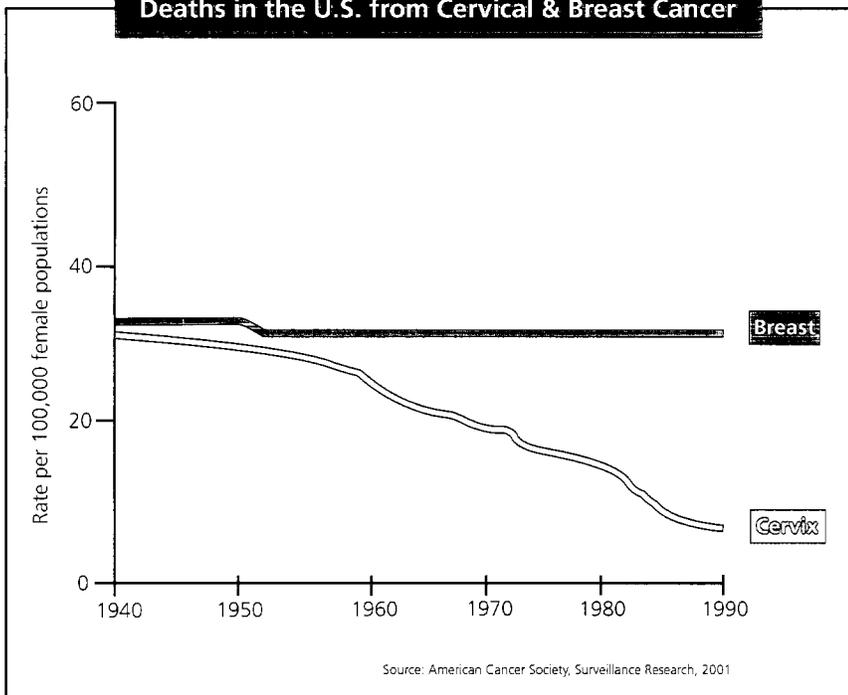


## Vision, Commitment, Success

Cytec Corporation has long been committed to the improvement of women's health and that commitment is expanding as we widen our scope with new products. Cytec's flagship product, the ThinPrep Pap Test, continues to gain acceptance. Additionally, the Company is moving towards a new vision of computerized cytology imaging with the development of the ThinPrep Imaging System, an interactive computer system that is expected to assist cytotechnologists in the primary screening and diagnosis of ThinPrep Pap Test slides.

The success of the ThinPrep Pap Test forms the platform for Cytec's expansion into breast cancer risk assessment with the FDA-approved FirstCyte Ductal Lavage, which is designed to enhance the evaluation of risk for breast cancer. Ductal lavage is currently used for women who are at high risk for breast cancer and is expected to enable the detection of atypical changes in cells lining the milk ducts, where an estimated 95 percent of all breast cancers originate. With further opportunities for growth, including testing of human papillomavirus (HPV), chlamydia, and gonorrhea from the ThinPrep Pap Test vial, Cytec intends to continue its success and to establish the Company as the world leader in women's health and cancer diagnostics.

**Deaths in the U.S. from Cervical & Breast Cancer**



### Breast Cancer in the U.S.

- Breast cancer afflicts 1 out of 8 women.
- The American Cancer Society estimates that 203,500 new cases of breast cancer will be diagnosed in 2002.
- Breast cancer is the second leading cause of cancer death for U.S. women.

### Market Opportunity\*

- ThinPrep Pap Test worldwide market opportunity is \$1.0 billion.
- FirstCyte Ductal Lavage U.S. market opportunity is \$1.5-\$4.0 billion.

*The Pap test has helped to significantly reduce the incidence and mortality from cervical cancer. With Cytec's expansion into breast cancer risk assessment, the Company hopes to have an impact on breast cancer, which is a leading cancer cause of death among women in the United States.*

\* Company estimates

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

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934. [Fee Required]

For the Fiscal Year Ended: December 31, 2001

or

Transition Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934. [No Fee Required]

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-27558

CYTYC CORPORATION  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

02-0407755  
(IRS Employer Identification No.)

85 Swanson Road,  
Boxborough, Massachusetts  
(Address of principal executive offices)

01719  
(Zip Code)

Registrant's telephone number, including area code: (978) 263-8000

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

None

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

Common Stock, \$.01 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 the voting stock held by nonaffiliates of the registrant as of February 15, 2002 (based on the closing price as quoted by The Nasdaq Stock Market as of such date) was \$2,522,346,569. As of February 15, 2002, 121,676,149 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2001. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

## PART I

### Item 1. Business

#### The Company

Cytec Corporation (the "Company") designs, develops, manufactures and markets a sample preparation system for medical diagnostic applications. The Company's ThinPrep® System allows for the automated preparation of cervical cell specimens on microscope slides for use in cervical cancer screening, as well as for the automated preparation of other cell specimens on microscope slides for use in non-gynecological testing applications. On May 20, 1996, the Company received premarket approval ("PMA") from the United States Food and Drug Administration ("FDA") to market the ThinPrep System for cervical cancer screening as a replacement for the conventional Pap smear method. On November 6, 1996, the FDA cleared expanded product labeling for the ThinPrep System to include the claim that the ThinPrep System is significantly more effective in detecting Low Grade Squamous Intraepithelial Lesions ("LGSIL") and more severe lesions than the conventional Pap smear method in a variety of patient populations. The expanded labeling also indicates that the specimen quality using the ThinPrep System is significantly improved over that of the conventional Pap smear method. The Company believes that the ThinPrep System improves accuracy in the detection of cervical cancer and precancerous lesions by making the slide more representative of the patient's clinical condition, improving preservation of the sample, standardizing the presentation of cells on the slide, and reducing the presence of mucus, blood and other obscuring debris. On February 25, 1997, the FDA approved the Company's supplemental PMA application for use of a combination of an endocervical brush and spatula sampling devices, a commonly used method of collecting samples for conventional Pap smears.

On September 4, 1997, the FDA approved the Company's supplemental PMA application for the testing for the human papillomavirus ("HPV") directly from a single vial of patient specimen collected in ThinPrep solution using Digene Corporation's ("Digene") Hybrid Capture® HPV DNA Assay. In March 1999, the FDA approved the use of Digene's Hybrid Capture® II HPV DNA Assay from a single vial of patient specimen collected in ThinPrep solution.

The Company commenced the full-scale commercial launch of the ThinPrep System for cervical cancer screening in the United States in 1997 and in selected international markets in 1998. In May 2000, the FDA approved the ThinPrep® 3000 Processor, the Company's next-generation processor for automated sample preparation. In August 2001, the FDA approved the Company's PMA Supplement Application for the inclusion of data describing the detection of High-Grade Squamous Intraepithelial Lesions (HSIL) with the ThinPrep Pap Test. In December 2001, the Company submitted a supplemental PMA application to the FDA to allow for testing for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoea (NG) directly from the ThinPrep Pap Test vial using Roche Diagnostics Corporation ("RDC") COBAS Amplicor™ automated system. In January 2002, the Company submitted a PMA Application to the FDA for the ThinPrep® Imaging System™ to aid in cervical cancer screening.

#### Recent Acquisitions

In October 2001, the Company announced that it had entered into a definitive merger agreement to acquire all of the outstanding securities of Pro Duct Health, Inc. ("Pro Duct"), a privately held company that has developed a ductal lavage device to enhance the evaluation of risk for breast cancer. In November 2001, the Company completed its acquisition of Pro Duct by means of a merger of Pro Duct with and into Cytec Health Corporation, a wholly-owned subsidiary of Cytec Corporation. The Company intends to market the ductal lavage device as the ThinPrep Breast Test™, subject to required regulatory approvals.

On February 19, 2002, the Company announced that it had signed a definitive merger agreement to acquire all of the outstanding securities of Digene in an exchange offer transaction. The closing of the exchange offer is subject to the tender of over 50 percent of Digene's outstanding securities, regulatory approval and other customary closing conditions. Although the Company expects that its acquisition of Digene will close during the second quarter of 2002, the Company may not be able to complete the acquisition during the second quarter, or at all.

## Cervical Cancer

Cervical cancer is one of the most common cancers among women throughout the world. Cervical cancer is preceded by curable precancerous lesions that progress without symptoms over a period of years until they become invasive, penetrating the cervical epithelium (cellular covering) and entering the bloodstream or lymph system. In order to detect these precancerous lesions, gynecologists in the United States typically recommend annual screening examinations. If detected in the precancerous stage, virtually all cervical cancer cases are preventable. The treatment of cervical cancer after it reaches the invasive stage may require surgery, including a hysterectomy, and chemotherapy or radiation treatment, which are difficult, expensive and may not be successful.

The factors associated with the development of cervical cancer are believed to include early sexual activity, multiple sexual partners, cigarette smoking and immunosuppression. In addition, a number of recent studies have concluded that cervical cancer is strongly correlated to the presence of certain types of HPV. According to these studies, HPV DNA is present in most cases of precancerous lesions and in more than 90% of cases of intraepithelial and invasive cancer. Cervical lesions that are HPV-negative or lacking certain types of HPV are less likely to progress to cervical cancer.

## The Pap Smear

Cervical cancer screening has been conducted since the late 1940s using the Pap smear, a test developed by Dr. George Papanicolaou. In the United States, widespread and regular use of the Pap smear as a screening test has contributed to a greater than 70% decrease in mortality from cervical cancer in the past. The Pap smear is currently the most widely used screening test for the early detection of cancer in the United States.

## The Pap Smear Process

The Pap smear process involves the science of cytology, which is the microscopic interpretation of precancerous, malignant and other changes in cells. The conventional Pap smear process begins with the collection of a cervical specimen during a gynecological examination. To obtain a cervical cell sample, a sampling device, such as either a brush and spatula or a "broom-like" device, is used to scrape cells from the surface of the cervix. The sample is then manually smeared onto a clean microscope slide by the physician who must then spray the slide within a few seconds with a fixative agent to prevent damage to the cell specimen from air drying. The slide is then submitted to a clinical laboratory for manual microscopic examination.

At the laboratory, a cytotechnologist, a medical professional with special training in the examination and interpretation of human cells, conducts a microscopic review of a prepared slide to determine the adequacy of the sample and the presence of abnormal cells. In determining slide adequacy, cytotechnologists classify each slide in one of three categories: (i) satisfactory for evaluation, (ii) satisfactory but limited by ("SBLB") certain characteristics, or (iii) unsatisfactory for evaluation. The percentage of unsatisfactory and SBLB slides varies widely from laboratory to laboratory. In a 1991 study of 600 laboratories, it was reported that up to 20% of slides were classified as unsatisfactory and up to 40% were classified as SBLB. Frequent reasons for unsatisfactory or SBLB classifications include excess blood or mucus that impair viewing or too few cells per slide.

After determining the adequacy of the slide, the cytotechnologist manually screens each Pap smear slide with a microscope to differentiate diseased or abnormal cells from healthy cells based on size, shape and structural details of the cells and nuclei. Typically, each Pap smear slide is then classified in accordance with the Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses ("Bethesda System") into one of the following categories: (i) Negative; (ii) Atypical Squamous Cells of Undetermined Significance/Atypical Glandular Cells of Undetermined Significance ("ASCUS/AGUS"); (iii) Low Grade Squamous Intraepithelial Lesions ("LGSIL"); (iv) High Grade Squamous Intraepithelial Lesion ("HGSIL"); and (v) Carcinoma. Any slide classified as other than negative is considered abnormal and may be precancerous or cancerous. All abnormal slides are referred to a senior cytotechnologist and pathologist for further review and final diagnosis.

Notwithstanding the classifications imposed by the Bethesda System, the subjective nature of the classification of Pap smear specimens results in diagnoses that vary widely among cytotechnologists, pathologists and laboratories. In 1988, to address accuracy and quality control concerns, Congress adopted the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). CLIA requires cytology laboratories to perform proficiency testing and quality control by testing cytotechnologists in order to assure a minimum level of competence and expertise. In addition, the CLIA regulations currently limit the number of slides screened per day by a cytotechnologist to 100. Certain states have also adopted regulations further limiting the number of slides which can be manually examined per day by a cytotechnologist. As a further quality control measure, the CLIA regulations require that laboratories manually rescreen at least 10% of the slides that are initially classified as negative.

Other methods of rescreening are currently available, including computer imaging technologies that select certain negative slides or portions of negative slides for reexamination by the cytotechnologist. These computer-imaging technologies are intended to provide an additional quality control measure to help identify false negative diagnoses.

#### *Follow-Up Treatment of Abnormal Pap Smears*

Women with abnormal Pap smears may have to return to their physician's office for a repeat Pap smear or to undergo costly colposcopy and biopsy procedures. A colposcopy involves the physician using a device to visually examine the surface of the cervix, and if necessary, performing a biopsy. Treatment of early-stage non-invasive cervical cancer may be accomplished by procedures to remove the abnormal cells. Once the cancer reaches the invasive stage, the patient's chances for recovery are diminished and more radical treatment is typically required, such as a hysterectomy and chemotherapy or radiation therapy. These procedures may expose the patient to risk and cost and result in significant physical and psychological stress.

#### *Problems with the Conventional Pap Smear*

In spite of the success of the Pap smear in reducing deaths due to cervical cancer, the test has significant limitations, including inadequacies in sample collection and slide preparation, slide interpretation errors and the inability to use the specimen for additional diagnostic tests. These limitations result in a substantial number of inaccurate test results, including false negative diagnoses.

#### *False Negative Diagnoses*

The limitations of the conventional Pap smear method in sample collection, slide preparation and interpretation result in a substantial number of inaccurate test results in the form of false negative diagnoses. A false negative diagnosis may allow the disease to progress to a later-stage of development before being detected, thereby requiring a more expensive and invasive course of treatment and diminishing the likelihood of successful treatment. Reports of the false negative rate of the Pap test vary widely, between 5% and 55%. Past studies have suggested that approximately 50% of false negative diagnoses are attributable to inadequacies in sample collection and slide preparation and approximately 50% are attributable to slide interpretation errors. The most comprehensive literature survey to date was recently published by the Agency for Health Care Policy and Research (AHCPR), a division of the U.S. Department of Health and Human Services. The "Evaluation of Cervical Cytology" evidence report concluded that the false negative rate for the conventional Pap smear is approximately 49% and that about two-thirds of false negatives are due to sampling error and the remaining one-third due to detection error.

#### *Inadequacies in Sample Collection and Slide Preparation*

There are a variety of difficulties with current methods of cell collection, cell transfer and slide preparation. These difficulties include cell loss, improper fixation of the cells (typically, from air-drying), thick and uneven

smearing of cells on the slide, and excess blood, mucus and other obscuring debris on the slide. A study published in the American Journal of Clinical Pathology in February 1994 reported that as much as 80% of the sample taken from a patient using the conventional Pap smear method is not transferred to the microscope slide and remains on the discarded collection device. This discarded portion of the sample may contain the abnormal cells necessary for an accurate diagnosis. In addition to the problem of cell transfer, the conventional Pap smear method produces inconsistent and non-uniform slides with extreme variability in quality, making examination difficult. The Company believes that these limitations are responsible for a large percentage of slides being classified as SBLB. These slides are more difficult to interpret and increase the uncertainty of an accurate diagnosis. Consequently, patients are often subjected to the inconvenience and expense of return office visits for repeat testing and to the anxiety resulting from the inconclusive nature of the initial test. The Company believes that these repeat visits and examinations also result in significant costs to the healthcare system.

#### *Slide Interpretation Errors*

The process of screening and interpreting a manually prepared Pap smear is complex and tedious. This process requires constant vigilance, as approximately 90% to 95% of all Pap smear diagnoses in the United States are negative. In addition, the process is prone to error as a result of the complexity of properly evaluating and categorizing subtle and minute changes in cellular or nuclear detail. The screening process requires intense visual review through a microscope of a large volume of slides, each of which typically contains 50,000 to 300,000 cervical cells. The small percentage of Pap smears that contain any abnormality may, in turn, contain only a small number of abnormal cells among the vast number of normal cells. Cytotechnologists generally review each slide for approximately five to ten minutes and may review up to 100 slides per day. All of these factors contribute to the incidence of false negative diagnoses.

#### *Lack of Additional Testing Capability*

The conventional Pap smear method does not permit additional or adjunct testing from the original patient sample. The ability to produce multiple slides from a single sample could be used by clinical laboratories for follow-up testing, quality control or proficiency testing. Further, the conventional Pap smear method requires the patient to be called back to the physician's office to provide a second sample if additional testing, such as HPV testing, is desired. The Company believes that the ability to test for HPV directly from the ThinPrep collection vial has the potential for substantial healthcare cost savings through reduced costly management of borderline cervical abnormalities.

#### *The ThinPrep System*

The Company believes that the ThinPrep System offers a number of benefits which address limitations of the conventional Pap smear method, including improved accuracy in the detection of cervical cancer and precancerous lesions, standardization and simplification of the sample preparation process, the ability to permit multiple tests to be conducted from a single sample and improved productivity in screening by reducing cytotechnologist fatigue and the time required to examine each slide. In August 1997, *Obstetrics & Gynecology*, a preeminent, widely read, peer-reviewed journal on women's healthcare issues, published a major study describing the effectiveness of the ThinPrep® Pap Test™ in screening for cervical cancer.

The ThinPrep System, which was cleared for marketing as a replacement for the conventional Pap smear method for cervical cancer screening by the FDA on May 20, 1996, consists of the ThinPrep® Processor and related disposable reagents, filters and other supplies. The ThinPrep System is designed to reduce the incidence of false negative diagnoses, improve slide quality, reduce inconclusive SBLBs and enable a single sample to be used for additional diagnostic testing. On November 6, 1996, the FDA cleared expanded product labeling for the ThinPrep System to include the claim that the ThinPrep System is significantly more effective in detecting LGSIL and more severe lesions than the conventional Pap smear method in a variety of patient populations. This expanded labeling also indicates that the specimen quality using the ThinPrep System is significantly improved

over that of the conventional Pap smear method. In February 1997, the Company received FDA approval of the Company's supplemental PMA application for the use of a combination of an endocervical brush and spatula sampling devices, a commonly used method of collecting samples for conventional Pap smears. In September 1997, the FDA approved the Company's supplemental PMA application for the testing for HPV directly from a single vial of patient specimen collected in a ThinPrep solution using the Hybrid Capture HPV DNA Assay of Digene. In March 1999, the FDA approved the use of Digene's Hybrid Capture II HPV DNA Assay from a single vial of patient specimen collected in ThinPrep solution. The Company commenced the full-scale commercial launch of the ThinPrep System for cervical cancer screening in the United States in 1997 and in selected international markets in 1998. In May 2000, the FDA approved the ThinPrep 3000 Processor, the Company's next-generation processor for automated sample preparation. In August 2001, the FDA approved the Company's PMA Supplement Application for the inclusion of data describing the detection of High-Grade Squamous Intraepithelial Lesions (HSIL) with the ThinPrep Pap Test. In December 2001, the Company submitted a supplemental PMA application to the FDA to allow for testing for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoea (NG) directly from the ThinPrep Pap Test vial using RDC's COBAS AmpliCor™ automated system. In January 2002, the Company submitted a PMA Application to the FDA for the ThinPrep Imaging System to aid in cervical cancer screening.

The ThinPrep process begins with the patient's cervical sample being taken by the physician using a cervical sampling device which, rather than being smeared on a microscope slide, is rinsed in a vial filled with the Company's proprietary PreservCyt® Solution. This enables virtually all of the patient's cell sample to be preserved before the cells can be damaged by air drying. The ThinPrep specimen vial is then labeled and sent to a laboratory equipped with a ThinPrep Processor for slide preparation and screening.

At the laboratory, the ThinPrep specimen vial is inserted into a ThinPrep Processor, a proprietary sample preparation device which automates the process of preparing cervical specimens. Once the vial is inserted into the ThinPrep Processor, a gentle dispersion step breaks up blood, mucus, non-diagnostic debris and large sheets of cells and homogenizes the cell population. The cells are then automatically collected on the Company's proprietary TransCyt® Filter, which incorporates an eight micron membrane specifically designed to collect abnormal and cancerous cells. The ThinPrep Processor constantly monitors the rate of flow through the TransCyt Filter during the collection process in order to prevent the cellular presentation from being too scant or too dense. A thin layer of cells is then transferred to a glass slide in a 20 mm-diameter circle and the slide is automatically deposited into a preservative solution.

The Company's proprietary reagents and supplies include PreservCyt Solution to collect and transport cervical samples to the laboratory for optimal cell preservation and TransCyt Filters to collect cells and remove non-diagnostic debris and mucus. The Company also sells ThinPrep® Microscope Slides, high-quality microscope slides manufactured to the Company's specifications, which improve cell adhesion to the slide.

#### Clinical Trial Results

In October 1995, the Company completed the clinical trial used to support its PMA application, which was a blinded, split-sample study performed at six clinical sites in the United States, including three screening centers and three hospital sites. A total of 6,747 patients were included. The study compared the effectiveness of the ThinPrep System to the conventional Pap smear method for the detection of precancerous lesions of the cervix. Specimen adequacy was also compared.

The results from the three screening centers indicated a 65% improvement in the detection of disease, while in the three hospital sites in which patients had historically exhibited high prevalence rates of cervical abnormalities, the ThinPrep method demonstrated a 6% improvement. In May 1996, based on the clinical trial results, the FDA approved the ThinPrep 2000 System as a replacement for the conventional Pap smear method in screening for the presence of atypical cells, cervical cancer, and its precursor lesions. After further analysis of the clinical trial data, in November 1996, the FDA cleared expanded product labeling to include that the ThinPrep System is significantly more effective in detecting LGSIL and more severe lesions than the conventional Pap

smear method in a variety of patient populations. The FDA also cleared expanded product labeling to include that the specimen quality using the ThinPrep System is significantly improved over that of the conventional Pap smear method. In May 2000, the FDA approved the ThinPrep 3000 Processor, the Company's next generation processor for automated sample preparation. In August 2001, the FDA approved a PMA Supplement allowing inclusion of data describing the detection of High-Grade Squamous Intraepithelial Lesions (HSIL) with the ThinPrep Pap Test. The data, from a multi-site clinical outcomes trial, is now included in the Company's Package Insert that accompanies the ThinPrep System.

Following initial FDA approval of the ThinPrep System in May 1996, the Company conducted a multi-site direct-to-vial clinical study to evaluate the ThinPrep 2000 System versus the conventional Pap smear for the detection of High-Grade Squamous Intraepithelial and more severe lesions (HSIL+). Two types of patient groups were enrolled in the trial from ten leading academic hospitals in major metropolitan areas throughout the United States. From each site, one group consisted of patients representative of a routine screening population and the other group was made up of patients representative of a referral population enrolled at the time of colposcopic examination. The ThinPrep specimens were collected prospectively and compared against a historical control cohort. The historical cohort consisted of data collected from the same clinics and clinicians (if available) used to collect the ThinPrep specimens. These data were collected sequentially from patients seen immediately prior to the initiation of the study. The results from this study showed a detection rate of 511/20,917 for the conventional Pap smear versus 399/10,226 for the ThinPrep slides. For these clinical sites and these study populations, this indicates a 59.7 percent ( $p < 0.001$ ) increase in detection of HSIL+ lesions for the ThinPrep System.

In July 1999, the Company announced that it had successfully completed feasibility studies of the ThinPrep Imaging System to aid in cervical cancer screening and in December 2000 began clinical trials. In January 2002, the Company submitted a PMA Application to the FDA for the ThinPrep Imaging System. This PMA Application is supported by a prospective, multi-center clinical study that evaluated the performance of the ThinPrep Imaging System in direct comparison to a manual review method. More than 9,500 patients from both low-risk and high-risk populations were included in the study. The ThinPrep Imaging System is an interactive computer system that the Company believes will assist cytotechnologists in the primary screening and diagnosis of ThinPrep Pap Test slides. The system combines imaging technology to identify diagnostic fields of interest with automated microscope stage movements to facilitate locating these fields. The system is expected to increase a cytology laboratory's screening productivity while leveraging the increased sensitivity of the ThinPrep Pap Test.

In December 2001, the Company submitted a supplemental PMA application to the FDA to allow for testing for CT/NG directly from the ThinPrep Pap Test vial using RDC's COBAS Amplicor™ automated system.

There can be no assurance that the Company will obtain necessary regulatory approvals for the ThinPrep Imaging System, RDC's CT/NG test from the ThinPrep vial, or any other new products or applications.

Since FDA approval of the ThinPrep System in May of 1996, a number of studies have been published or presented that evaluate the ThinPrep Pap Test. To date, more than 30 major studies evaluating the performance of the ThinPrep Pap Test compared to the conventional Pap smear have been published in peer-reviewed journals. The studies have included more than 300,000 patients in the ThinPrep Pap Test cohort and have been conducted in every region of the United States, as well as Europe, Asia, Central America and Australia. In total, more than 70 studies have been published demonstrating a wide range of benefits including increased disease detection, reduction of equivocal diagnoses, improved specimen adequacy, adjunctive molecular testing, morphology assessment, and cost effectiveness.

#### Non-Gynecological Cytology

In May 1991, the Company began commercial shipments of the ThinPrep® Processor to cytology laboratories in the United States for use in non-gynecological testing applications. Non-gynecological specimens

include sputum; voided and catheterized urine; body fluids such as peritoneal fluid, ascites fluid, or cerebrospinal fluid; brushing of respiratory or gastrointestinal tracts; and fine needle aspiration specimens obtained from a variety of sources such as the breast, thyroid, lung or liver. These samples are evaluated in patients in whom malignancy is strongly suspected or as follow-up information in patients previously diagnosed and treated for cancer.

#### Marketing and Sales

The Company's marketing and sales strategy is to achieve broad market acceptance of the ThinPrep System for cervical cancer screening. A critical element of its strategy is to utilize the results of the Company's 1995 clinical trial and expanded FDA labeling to demonstrate the safety and efficacy of the ThinPrep System to healthcare providers, third-party payors and clinical laboratories. The Company believes that coordination of the activity of these three market segments is necessary to achieve the desired level of market penetration of the ThinPrep System. In 1997, the Company implemented a full-scale commercial launch of the ThinPrep System in the United States with its direct marketing and sales force organization, complemented by the initiation of strategic marketing relationships with third parties.

The Company continues to expand its direct marketing and sales organization in the United States, supported by customer and technical service representatives. The Company's direct marketing and sales organization focuses on the clinical and economic benefits of the ThinPrep System for healthcare providers, third-party payors and clinical laboratories. The Company designs its marketing programs to establish and reinforce the recognition of its corporate and product names through investments in medical advertising, direct mail, focused medical educational symposia, trade shows and other promotional activities. The Company has also initiated an education and training program which will be offered to accredited cytology schools across the United States.

In January 2000, the Company entered into a supply and co-marketing agreement with Quest Diagnostics Incorporated ("Quest") to market the Company's ThinPrep Pap Test as Quest's exclusive liquid-based cervical cancer screening methodology.

In October 2000, the Company entered into an agreement with RDC, exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for chlamydia and gonorrhea using RDC's COBAS® AMPLICOR® CT/NG Test directly from the ThinPrep collection vial. The companies also intend to explore the potential for collaborating on a portfolio of additional screening and diagnostic tests based on the companies' respective technologies.

In January 2001, the Company entered into an agreement with Digene, exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for human papillomavirus (HPV) using Digene's Hybrid Capture® II HPV DNA Assay directly from the ThinPrep collection vial. The co-promotion program has focused on promoting Digene's HPV DNA test, using the residual material in ThinPrep collection vials, as the optimal patient management strategy for borderline cytology results.

Following the initial market launch of the ThinPrep product in the United States, the Company has more recently initiated its marketing and sales efforts in Europe and Asia Pacific. The Company established subsidiaries in Switzerland and Australia in 1997, in France and Italy in 1998, in Canada and the United Kingdom in 1999 and in Germany in 2001 to handle sales, service, training and distribution to clinical laboratories. The Company's strategy is to establish a worldwide selling channel appropriate for developing an international customer-base, taking into consideration factors such as government regulations, screening cycles and clinical practices of the particular country or region. The Company is also evaluating the use of direct and indirect international sales channels, including contract sales organizations, distributors and marketing partners.

The Company believes that both domestic and international sales efforts will continue to involve a lengthy process, requiring the Company to educate healthcare providers, clinical laboratories, and third-party payors

regarding the clinical benefits and cost-effectiveness of the ThinPrep System and any other new products and applications, such as the ductal lavage device obtained by the Company in its acquisition of Pro Duct. The Company's success and growth will depend to a large extent on market acceptance of the ThinPrep System and any such other products and applications among healthcare providers, third-party payors and clinical laboratories. The Company will continue to sell ThinPrep Processors to customers and charge separately for related disposable reagent filters and supplies. In the past, the Company has offered discounts to stimulate demand for the ThinPrep System and may elect to do so in the future, which discounts could have a material adverse effect on the Company's business, financial condition and results of operations.

In order to effectively market the ThinPrep System for cervical cancer screening and any other new products and applications, such as the ductal lavage device, the Company will need to continue to increase its marketing and sales capabilities. No assurance can be given that the Company's direct sales force or strategic marketing relationships will succeed in promoting the ThinPrep System or any other new products or applications to healthcare providers, third-party payors or clinical laboratories, or that additional marketing and sales channels will be successfully established. While the Company is currently evaluating marketing and sales channels abroad, including contract sales organizations, distributors and marketing partners, the Company has established very limited foreign sales channels. There can be no assurance that the Company will be able to recruit and retain skilled marketing, sales, service or support personnel or foreign distributors, or that the Company's marketing and sales efforts will be successful. The Company's marketing success in the United States and abroad will depend on whether it can obtain required regulatory approvals, successfully demonstrate the cost-effectiveness of the ThinPrep System and any such other new products and applications, further develop its direct sales capability and establish arrangements with contract sales organizations, distributors and marketing partners. Failure to successfully expand its marketing and sales capabilities in the United States or establish its international marketing and sales organization would have a material adverse effect on the Company's business, financial condition and results of operations.

#### Third-Party Reimbursement

The Company intends to focus on obtaining coverage and reimbursement from major national and regional managed care organizations and insurance carriers throughout the United States. Most of the third-party payor organizations independently evaluate new diagnostic procedures by reviewing the published literature and the Medicare coverage and reimbursement policy on the specific diagnostic procedure. To assist the third-party payors in their respective evaluations of the ThinPrep System, the Company provides scientific and clinical data to support its claims of the safety and efficacy of the ThinPrep System. The Company believes that the ThinPrep System will allow for earlier detection of LGSIL and more severe lesions and result in less aggressive and costly treatment procedures. In addition, the Company expects that the ThinPrep System will significantly improve specimen adequacy, thereby reducing repeat office visits and test procedures and thus overall healthcare management costs. The Company will focus on earlier disease detection and cost savings benefits in establishing reimbursement for the ThinPrep method for cervical cancer screening.

The cost per ThinPrep Pap Test, plus a laboratory mark-up, is billed by laboratories to third-party payors or patients and typically results in a higher cost than the current charge for conventional Pap tests. Although a number of managed care organizations have added the ThinPrep Pap Test to their coverage, there can be no assurance that third-party payors will provide or continue to provide such coverage, that reimbursement levels will be adequate or that healthcare providers or clinical laboratories will use the ThinPrep System for cervical cancer screening in lieu of the conventional Pap smear method. In addition, the Company will be required to secure adequate third-party reimbursement for any new products it develops or obtains, including the ductal lavage device obtained in the Company's acquisition of Pro Duct in November 2001.

There is significant uncertainty concerning third-party reimbursement for the use of any medical device incorporating new technology. Reimbursement by a third-party payor depends on a number of factors, including the level of demand by healthcare providers and the payor's determination that the use of the product represents a

clinical advance compared to current technology and is safe and effective, medically necessary, appropriate for specific patient populations and cost-effective. Since reimbursement approval is required from each payor individually, seeking such approvals is a time-consuming and costly process, which requires the Company to provide scientific and clinical data to support the use of its products to each payor separately. There can be no assurance that third-party reimbursement will be or remain available for the ThinPrep System, the Pro Duct ductal lavage device, or any other products that may be obtained or developed by the Company, or that such third-party reimbursement will be adequate.

Since January 1, 1998, the Company's laboratory customers have been able to request reimbursement for the ThinPrep Pap Test from health insurance companies and the Center for Medicare and Medicaid Services ("CMS") using a newly assigned Common Procedure Technology ("CPT") code specifically for liquid-based monolayer cervical cell specimen preparation. CPT codes are assigned, maintained and revised by the CPT Editorial Board, which is administered by the American Medical Association, and are used in the submission of claims to third-party payors for reimbursement for medical services. CMS has established a national fee of \$28 for the CPT codes describing the ThinPrep Pap Test. This reimbursement level is nearly double the level of reimbursement for the conventional Pap smear.

The Company's direct sales force is actively working with current laboratory customers and health insurance companies to facilitate implementation and reimbursement under the CPT code. As of December 31, 2001, based on information provided to the Company, the Company believes that substantially all of the 367 health insurance companies which announced coverage of the ThinPrep Pap Test have implemented the new CPT code and have established a reimbursement amount. There are approximately six hundred managed care organizations and other third-party payors in the United States. There can be no assurance, however, that the new CPT code will be successfully implemented by additional third-party payors, that any reimbursement delays will be successfully reduced, or that reimbursement levels under the new CPT code will be or remain adequate.

The Company has limited experience in obtaining reimbursement for its products in the United States or other countries. In addition, third-party payors are routinely limiting reimbursement and coverage for medical devices and in many instances are exerting significant pressure on medical suppliers to lower their prices. Lack of or inadequate reimbursement by government and other third-party payors for the Company's products would have a material adverse effect on the Company's business, financial condition and results of operations. Further, outside of the United States, healthcare reimbursement systems vary from country to country, and there can be no assurance that third-party reimbursement will be made available at an adequate level, if at all, for the Company's products under any other reimbursement system.

#### Manufacturing

In January 2000, the Company acquired Acu-Pak, Inc. ("Acu-Pak"), a contract packager in Londonderry, New Hampshire that was, prior to the acquisition, manufacturing, filling and distributing vials containing the Company's solutions for all of its ThinPrep line of products. The Company currently leases approximately 97,000 square feet of commercial space in Boxborough, MA and believes that its existing facility, along with the Acu-Pak production facility consisting of approximately 45,000 square feet of commercial space, are adequate to meet the existing production requirements for the ThinPrep System. In November 2001, as part of its acquisition of Pro Duct, a manufacturer of medical devices in Menlo Park, California, the Company entered into a lease for a facility consisting of approximately 35,000 square feet. The lease of this facility terminates on April 30, 2003. The Company has subleased approximately 17,000 square feet of office space in Menlo Park, California to a third party for eighteen months ending April 30, 2003. In connection with the acquisition, the Company has committed to a plan to abandon the leased facilities. The Company has accrued approximately \$787,000 for the abandonment of the leased facility, representing the present value of future minimum lease payments less estimated sub-lease receipts. The Company believes that its facilities in Massachusetts and New Hampshire will satisfy its operational requirements for the foreseeable future.

The Company has expanded its manufacturing capacity by adding approximately \$4.1 million of additional automated equipment, which was installed in late 2001. Of this amount, approximately \$3.8 million was paid in 2000 and approximately \$0.3 million was paid in 2001.

The Company's manufacturing process is subject to pervasive and continuing regulation by the FDA, including the FDA's Quality System Regulation ("QSR"). Failure to comply with such regulations would materially impair the Company's ability to achieve or maintain commercial-scale production. Further, any failure of the Company's equipment to perform to the Company's specifications could impair the Company's ability to produce adequate quantities of ThinPrep supplies. As a result, the Company may be subject to total or partial suspension of production, withdrawal of approval, and recall or seizure of products by the FDA in the event of product malfunction or failure.

In October 1997, the Company obtained ISO 9001 registration, an international quality standard. The Company has also met the applicable requirements to use the "CE" mark for its ThinPrep System. There can be no assurance that the Company will be able to maintain compliance with ISO or CE mark requirements. Failure to maintain compliance with the applicable manufacturing requirements of various regulatory agencies would have a material adverse effect on the Company's business, financial condition and results of operations.

Certain key components of the Company's ThinPrep System are currently provided to the Company by single sources. In the event that the Company is unable to obtain sufficient quantities of such components on commercially reasonable terms, or in a timely manner, the Company would not be able to manufacture its products on a timely and cost-competitive basis, which would have a material adverse effect on the Company's business, financial condition and results of operations.

#### Research and Development

The Company's core research and development strategy is to continue to develop innovative medical diagnostic applications of the ThinPrep technology and to continue to enhance the ThinPrep System. The Company has established a program to further enhance and automate the ThinPrep Processor. The Company's next generation instrument, the ThinPrep 3000 Processor, was designed to provide batch processing and walk-away capability by increasing capacity to 80 sample vials and more fully automating the slide preparation process. In May 2000, the FDA approved the ThinPrep 3000 Processor, which is now commercially available.

The Company is also evaluating additional diagnostic applications of its ThinPrep technology in testing for the presence of other types of cancers and sexually transmitted diseases. The clinical laboratory companies have worked with the Company on marketing and sales programs, which generally involve joint marketing geared toward promoting the Company's products to physicians and third-party payors.

In January 2000, the Company entered into a supply and co-marketing agreement with Quest to market the ThinPrep Pap Test as Quest's exclusive liquid-based cervical cancer screening methodology.

In October 2000, the Company entered into an agreement with RDC, exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for chlamydia and gonorrhea using RDC's COBAS® AMPLICOR® CT/NG Test directly from the ThinPrep collection vial. The companies also intend to explore the potential for collaborating on a portfolio of additional screening and diagnostic tests based on the companies' respective technologies. In December 2001, the Company submitted a supplemental PMA application to the FDA to allow for testing for CT/NG directly from the ThinPrep Pap Test vial using RDC's COBAS Amplicor™ automated system.

In January 2001, the Company entered into an agreement with Digene, exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for human papillomavirus (HPV) using Digene's Hybrid Capture® II HPV DNA Assay directly from the ThinPrep collection vial. The co-promotion program is initially

focusing on promoting Digene's HPV DNA test and using the residual material in ThinPrep collection vials as the optimal patient management strategy for borderline cytology results.

The Company has not yet determined additional applications, if any, it will seek to develop and commercialize. There can be no assurance that the Company will be successful in developing or marketing additional applications. Furthermore, any additional applications may require submission of a PMA application or PMA supplement prior to the marketing of such applications. There can be no assurance that the FDA would approve such submissions on a timely basis, if at all.

In January 2002, the Company submitted a PMA Application to the FDA for the ThinPrep Imaging System to aid in cervical cancer screening. There can be no assurance that the Company will obtain necessary regulatory approvals.

The Company's expenditures for research and development (which includes clinical trials, regulatory affairs and engineering) were approximately \$13.4 million, \$14.2 million, and \$19.0 million for the years ended December 31, 1999, 2000 and 2001, respectively. Research and development for the 2001 period excludes a one-time charge of \$56.0 million for in-process research and development related to the Pro Duct acquisition.

### Government Regulation

The manufacture and sale of medical diagnostic devices intended for commercial use are subject to extensive governmental regulation in the United States and in other countries. The Company's existing products, including the ThinPrep System and the Pro Duct ductal lavage device, are regulated in the United States as medical devices by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDC Act") and generally require premarket approval through the filing of a PMA prior to commercial distribution. In addition, certain material changes or modifications to medical devices also are subject to the FDA review and approval. Pursuant to the FDC Act, the FDA regulates the research, testing, manufacture, safety, labeling, storage, record keeping, advertising, distribution and production of medical devices in the United States. Non-compliance with applicable requirements of the FDC Act can result in the failure of the government to grant premarket approval for devices, withdrawal of clearances or approvals, total or partial suspension of production, fines, injunctions, civil penalties, recall or seizure of products, and criminal prosecution.

The regulatory approval process can be expensive, lengthy and uncertain. There can be no assurance that the Company will be able to obtain necessary regulatory approvals for any proposed future products or modifications of existing products. The failure to obtain approvals, loss of previously received approvals, or failure to comply with existing or future regulatory requirements, would have a material adverse effect on the Company's business, financial condition and results of operations.

The FDA's regulations require agency approval of a PMA supplement for certain changes if they affect the safety and effectiveness of the device, including, but not limited to, new indications for use; labeling changes; the use of a different facility or establishment to manufacture, process, or package the device; changes in manufacturing facilities, methods, or quality control systems; and changes in performance or design specifications.

The ThinPrep System for cervical cancer screening received PMA approval in May 1996. In May 2000, the FDA approved the ThinPrep 3000 Processor, the Company's next generation processor for automated sample preparation.

In December 2001, the Company submitted a supplemental PMA application to the FDA to allow for testing for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoea (NG) directly from the ThinPrep Pap Test vial using RDC's COBAS Amplicor™ automated system. In January 2002, the Company submitted a PMA Application to the FDA for the ThinPrep Imaging System. These applications have not received regulatory approval to date.

There can be no assurance that such approvals will be obtained on a timely basis, or at all. The Company anticipates that any other proposed uses for the ThinPrep System may require approval of a PMA supplement or a new PMA application.

On February 19, 2002, the Company announced that it had signed a definitive merger agreement to acquire all of the outstanding securities of Digene in an exchange offer transaction. If the merger is consummated, Digene will be a wholly owned subsidiary of the Company or will be merged with and into the Company. The Company has been advised that Digene filed a PMA Supplement with the FDA in October 2001 for approval to use Digene's Hybrid Capture 2 HPV DNA Test in conjunction with the Pap smear as a primary screen for cervical cancer and its precursors in women age 30 and older. The FDA panel hearing on Digene's PMA supplement is scheduled to be held in March 2002. The Company does not know whether the FDA will approve Digene's PMA Supplement. If the PMA Supplement is not approved or if such approval is substantially delayed, Digene's business, financial condition, and results of operations could be materially and adversely affected.

In July 1997, several petitions were filed requesting that the FDA review the PMA approval granted to the ThinPrep System. The petitions were filed pursuant to a provision of the FDC Act permitting any interested party to initiate a process by which the FDA may review an approval order and may issue an order affirming, reversing or modifying the approval. The Company responded to the petitions by submitting comments in December 1997 arguing that the FDA should deny them.

In April 1999, the FDA ruled on the petitions objecting to the approval of the ThinPrep Pap Test. In a letter addressed to petitioners, and copied to Cytoc, the FDA concluded: "It would serve no useful purpose to convene an advisory committee of experts to consider the objections raised in the petitions." The FDA addressed each of the 10 objections raised by the seven petitioners. In each instance, the agency concluded that there was no justification for review.

The ThinPrep System is, and any other products manufactured or distributed by the Company pursuant to an approved PMA application or supplements will be, subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experience with the use of the device, postmarket surveillance, postmarket registration and other actions as deemed necessary by the FDA. The Company is also subject to FDA inspection for compliance with regulatory requirements. Product labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. Products may only be promoted by the Company and any of its distributors for their approved indications. No assurance can be given that modifications to the labeling which may be required by the FDA in the future will not adversely affect the Company's ability to market or sell the ThinPrep System, the Pro Duct ductal lavage device, or any other products developed or obtained by the Company.

The Company also is subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that the Company will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon the Company's business, financial condition and results of operations.

Sales of medical devices outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain approval to market and sell the ThinPrep System from a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. No assurance can be given that such foreign regulatory approvals will be granted on a timely basis, or at all. In addition, there can be no assurance that the Company will meet the FDA's export requirements or receive FDA export approval when such approval is necessary, or that countries to which the devices are to be exported will approve the devices for import. Failure of the Company to meet the FDA's export requirements or obtain FDA export approval when required to do so, or to obtain approval for import, could have a material adverse effect on the Company's business, financial condition and results of operations.

The laboratories that would purchase the ThinPrep System are subject to extensive regulation under CLIA, which requires laboratories to meet specified standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The Company believes that the ThinPrep device operates in a manner that will allow laboratories purchasing the device to comply with CLIA requirements. However, there can be no assurance that adverse interpretations of current CLIA regulations or future changes in CLIA regulations would not have an adverse effect on sales of the ThinPrep System.

#### **Patents, Trademarks, Copyrights, Licenses and Proprietary Rights**

The Company relies on a combination of patents, trademarks, trade secrets, copyrights and confidentiality agreements to protect its proprietary technology, rights and know-how. The Company pursues patent protection in the United States and files corresponding patent applications in certain foreign jurisdictions. The Company holds seventeen issued United States patents, eleven pending United States patent applications, and corresponding foreign patents or patent applications relating to various aspects of its ThinPrep technology. As part of the Company's acquisition of Pro Duct, the Company acquired an interest in certain United States patents and patent applications, together with certain corresponding foreign counterparts, owned or licensed by Pro Duct, relating to various aspects of the Pro Duct ductal lavage technology. There can be no assurance, however, that pending patent applications will ultimately issue as patents or that the claims allowed in any of the Company's existing or future patents will provide competitive advantages for the Company's products or will not be successfully challenged or circumvented by competitors. Under current law, certain patent applications filed with the United States Patent and Trademark Office before November 29, 2000 may be maintained in secrecy until a patent is issued. Patent applications filed with the United States Patent and Trademark Office on or after November 29, 2000, as well as patent applications filed in foreign countries, may be published some time after filing but prior to issuance. The right to a patent in the United States is attributable to the first to invent, not the first to file a patent application. The Company cannot be sure that its products or technologies do not infringe patents that may be granted in the future pursuant to pending patent applications or that its products do not infringe any patents or proprietary rights of third parties. In the event that any relevant claims of third-party patents are upheld as valid and enforceable, the Company could be prevented from selling its products or could be required to obtain licenses from the owners of such patents or be required to redesign its products to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be on terms acceptable to the Company or that the Company would be successful in any attempts to redesign its products or processes to avoid infringement. The Company's failure to obtain these licenses or to redesign its products would have a material adverse effect on the Company's business, financial condition and results of operations.

On February 19, 2002, the Company announced that it had signed a definitive merger agreement to acquire all of the outstanding securities of Digene in an exchange offer transaction. If the merger is consummated, Digene will be a wholly owned subsidiary of the Company or will be merged with and into the Company. The Company has been advised that Digene may not have rights under some patents or patent applications related to its products or product candidates that are held by third parties, and may need to obtain such rights in order to begin or continue selling a product. Digene may be unable to obtain such rights on commercially reasonable terms or at all. Digene has in-licensed patents to a number of cancer-causing human papillomavirus types which, together with the patents to cancer-causing human papillomavirus types that it owns, may provide it with a competitive advantage. Digene may lose any such competitive advantage if these licenses terminate or if the patents licensed thereunder expire or are declared invalid. In addition, Digene may infringe the intellectual property rights of third parties, which could result in expensive intellectual property litigation and could prevent the development or marketing of current or proposed products.

Digene has received inquiries regarding possible patent infringements relating to, among other things, aspects of its Hybrid Capture technology. Based upon information provided by Digene, the Company believes that the patents of others to which these inquiries relate are either not infringed by Digene's Hybrid Capture technology or are invalid. However, there can be no assurance that such claims will not be asserted and, if

asserted, such claims may require Digene to enter into a royalty-bearing license or may prevent the development and marketing of any current or proposed product of Digene. Digene also may be forced to initiate or respond to expensive legal proceedings to protect Digene's patent position or other proprietary rights.

There can be no assurance that the obligations of employees of the Company and third parties with whom the Company has entered into confidentiality agreements to maintain the confidentiality of the Company's trade secrets and proprietary information, will effectively prevent disclosure of the Company's confidential information or provide meaningful protection for the Company's confidential information if there is unauthorized use or disclosure, or that technology similar to the Company's will not be independently developed by the Company's competitors. In addition, the Company is the exclusive perpetual worldwide licensee of certain patented technology from DEKA for use in the field of cytology related to the fluid pumping system used in the ThinPrep System. The Company is obligated to pay royalties equal to 1% of net sales of the ThinPrep Processor, filter cylinder disposable products which are used in the ThinPrep System, and improvements made by the Company relating to such items. The license provides that it may only be terminated (i) by mutual written consent of both parties or (ii) by DEKA on written notice to the Company in the event that the license is assigned to other than a single acquiror without the consent of DEKA. Failure by the Company to maintain rights to such technology could have a material adverse effect on the Company's business, financial condition and results of operations. The Company also holds unregistered copyrights on documentation and operating software developed by it for the ThinPrep System. The Company presently has several trademarks, some of which have been registered with the United States Patent and Trademark Office. There can be no assurance that any copyrights or trademarks owned by the Company will provide competitive advantages for the Company's products or will not be challenged or circumvented by its competitors.

Litigation may be necessary to defend against claims of infringement, or to enforce patents, copyrights, trademarks or trade secrets of the Company which could result in substantial cost to, and diversion of effort by, the Company. (See "Legal Proceedings".) In addition, the laws of some foreign countries do not protect the Company's proprietary rights to the same extent as do the laws of the United States.

### Competition

The development, FDA approval and commercial marketing of competing systems for cervical cancer screening could have a material adverse effect on the Company's business, financial condition and results of operations. The Company faces direct competition from a number of publicly-traded and privately-held companies, including other manufacturers of thin layer slide preparation systems. Many of the Company's existing and potential competitors have substantially greater financial, marketing, sales, distribution and technical resources than the Company, and more experience in research and development, clinical trials, regulatory matters, manufacturing and marketing. In addition, many of these companies may have established third-party reimbursement for their products. Several established medical device manufacturers produce thin layer slide preparation systems for use in non-gynecological testing applications, at least one of which has achieved brand-name recognition and significant penetration in the non-gynecological cytology market. In June 1999, AutoCyte, Inc., a competitor of the Company, received FDA approval to market its slide preparation system. In September 1999, AutoCyte, Inc. effected a merger with NeoPath, Inc., another competitor of the Company and a company that has received FDA approval for a computer imaging system for primary screening of Pap smears. The combined company was renamed TriPath Imaging, Inc. In addition to direct competition, the Company faces indirect competition from companies which currently market imaging systems to initially evaluate conventional pap smears (primary screening method) or to reexamine or rescreen conventional Pap smears previously diagnosed as negative. The Company believes that these systems, as currently sold, could not be used with the ThinPrep System, and, therefore, if such systems are installed at or used by hospitals and reference laboratories, the Company's ability to market its products to such hospitals and laboratories could be materially adversely affected.

The medical device industry is characterized by rapid product development and technological advances. The Company's products could be rendered obsolete or uneconomical by the introduction and market acceptance of competing products, by technological advances of the Company's current or potential competitors or by other approaches.

The Company competes on the basis of a number of factors, including manufacturing efficiency, marketing and sales capabilities and customer service and support. There can be no assurance that the Company will be able to compete successfully against current or future competitors or that competition, including the development and commercialization of new products and technology, will not have a material adverse effect on the Company's business, financial condition or results of operations.

#### Employees

As of December 31, 2001, the Company employed 554 persons. The Company is not subject to any collective bargaining agreements, has never experienced a work stoppage and considers its relations with its employees to be good.

#### Item 2. Properties

The Company's executive offices and manufacturing operations are located in Boxborough, Massachusetts in a leased facility consisting of approximately 97,000 square feet. The lease of this facility has a term of seven years beginning November 1997, with an option to extend the term for an additional five years. In January 2000, as part of its acquisition of Acu-Pak, a contract packager in Londonderry, New Hampshire, the Company acquired approximately 2.7 acres of land and facilities. In November 2001, as part of its acquisition of Pro Duct, a manufacturer of medical devices in Menlo Park, California, the Company entered into a lease for a facility consisting of approximately 35,000 square feet. The lease of this facility terminates on April 30, 2003. The Company has subleased approximately 17,000 square feet of office space in Menlo Park, California to a third party for eighteen months ending April 30, 2003. In connection with the acquisition, the Company has committed to a plan to abandon the leased facilities. The Company has accrued approximately \$787,000 for the abandonment of the leased facility, representing the present value of future minimum lease payments less estimated sub-lease receipts. The Company believes that its facilities in Massachusetts and New Hampshire will satisfy its operational requirements for the foreseeable future.

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

There were no matters submitted to a vote of security holders of the Company during the fourth quarter of the year ended December 31, 2001.

## PART II

### Item 5. Market for Registrant's Common Equity and Related Security Holder Matters

The Company's Common Stock is traded on The Nasdaq Stock Market under the symbol "CYTC". The following table sets forth, for the calendar periods indicated, the range of high and low sale prices for the Common Stock of the Company on The Nasdaq Stock Market, as adjusted to reflect both the two-for-one stock split in the form of a stock dividend paid in January 2000 to holders of record of the Company's Common Stock on January 14, 2000 and the three-for-one stock split in the form of a stock dividend paid in March 2001 to holders of record of the Company's Common Stock on February 16, 2001. These prices do not include retail mark-up, mark-down or commissions and may not represent actual transactions.

	High	Low
<b>2000:</b>		
First Quarter .....	\$19.25	\$ 7.94
Second Quarter .....	22.58	9.83
Third Quarter .....	23.48	11.25
Fourth Quarter .....	22.38	12.67
<b>2001:</b>		
First Quarter .....	\$22.67	\$13.63
Second Quarter .....	26.03	14.50
Third Quarter .....	27.01	18.67
Fourth Quarter .....	30.22	21.65
<b>2002:</b>		
First Quarter (through February 15, 2002) .....	\$26.49	\$19.24

On February 15, 2002, the last reported sales price of the Common Stock on the Nasdaq National Market was \$20.73 per share. As of February 15, 2002, there were approximately 533 holders of record of the Common Stock.

The Company has never declared or paid cash dividends. The Company currently intends to retain any earnings for use in its business and does not anticipate paying any cash dividends on its capital stock in the foreseeable future.

In December 1999, the Company's Board of Directors approved a two-for-one split of the Company's Common Stock. Payable in the form of a 100 percent stock dividend, all stockholders of record at the close of business on January 14, 2000 received one additional share of Common Stock for each share owned. The additional shares were distributed to stockholders on or about January 31, 2000. In January 2001, the Company's Board of Directors approved a three-for-one split of the Company's Common Stock. Payable in the form of a 200 percent stock dividend, all stockholders of record at the close of business on February 16, 2001 received two additional shares of Common Stock for each share owned. The additional shares were distributed to stockholders on or about March 2, 2001. All share numbers contained in this report on Form 10-K and the computations of basic and diluted net income (loss) per common share have been adjusted for all periods presented to reflect both the two-for-one and three-for-one stock splits.

On January 1, 2000, the Company issued to Quest a warrant to purchase up to 900,000 shares of the Company's Common Stock at an exercise price equal to \$10.14 per share. The warrant was issued in consideration of entering into a multi-year joint-marketing agreement. No underwriter was involved in the issuance of the warrant. On June 6, 2001, Quest exercised the warrant in full pursuant to the cashless exercise feature and the Company issued Quest 494,400 shares of the Company's Common Stock. Such issuance was made by the Company in reliance upon an exemption from the registration provisions of the Securities Act of 1933 set forth in Section 4(2) thereof as a transaction by an issuer not involving a public offering.

On November 30, 2001, the Company completed the acquisition of Pro Duct, a privately-held company that has developed a proprietary ductal lavage device for the early detection of breast cancer. The Company acquired all of the outstanding securities of Pro Duct by means of a forward triangular merger pursuant to which Pro Duct was merged with and into Cytoc Health Corporation, a wholly-owned subsidiary of the Company, with Cytoc Health Corporation surviving the merger and continuing in existence as a wholly-owned subsidiary of the Company.

In connection with the Company's acquisition of Pro Duct, the Company issued an aggregate of 5,000,000 shares of the Company's common stock and \$38.5 million in cash in exchange for all of the outstanding capital stock and vested options and warrants of Pro Duct. The Company also assumed all outstanding options to acquire Pro Duct common stock. No underwriters were involved in the Company's issuance of common stock to the Pro Duct securityholders, which was made by the Company in reliance upon an exemption from the registration provisions of the Securities Act of 1933 set forth in Section 4(2) thereof as a transaction by an issuer not involving a public offering.

#### Item 6. Selected Consolidated Financial Data

The selected consolidated financial data set forth below for each of the years ended December 31, 1999, 2000 and 2001 and at December 31, 2000 and 2001 are derived from consolidated financial statements of the Company audited by Arthur Andersen LLP, independent public accountants, which are included elsewhere herein. The consolidated selected financial data for the years ended December 31, 1997 and 1998 and at December 31, 1997, 1998 and 1999 are derived from consolidated financial statements of the Company audited by Arthur Andersen LLP which are not included herein. The selected consolidated financial data set forth below should be read in conjunction with the consolidated financial statements and related notes thereto and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

	Year Ended December 31,				
	1997	1998	1999	2000	2001
	(in thousands, except per share data)				
<b>Statements of Operations Data:</b>					
Net sales	\$ 26,347	\$ 44,264	\$ 81,100	\$142,065	\$220,993
Cost of sales	8,006	11,211	15,815	24,565	40,168
Gross profit	18,341	33,053	65,285	117,500	180,825
<b>Operating expenses:</b>					
Research and development	6,048	8,419	13,372	14,171	18,975
In-process research and development	—	—	—	—	56,000
Sales and marketing	31,761	35,332	44,017	55,162	59,161
General and administrative	7,746	8,372	6,765	13,872	16,987
Total operating expenses	45,555	52,123	64,154	83,205	151,123
Income (loss) from operations	(27,214)	(19,070)	1,131	34,295	29,702
Other income, net	5,142	7,341	4,639	4,721	8,006
Income (loss) before provision for income taxes	(22,072)	(11,729)	5,770	39,016	37,708
Provision for income taxes	—	—	130	853	25,073
Net income (loss)	<u>\$ (22,072)</u>	<u>\$ (11,729)</u>	<u>\$ 5,640</u>	<u>\$ 38,163</u>	<u>\$ 12,635</u>
Net income (loss) per common and potential common share (1):					
Basic	<u>\$ (0.22)</u>	<u>\$ (0.11)</u>	<u>\$ 0.05</u>	<u>\$ 0.34</u>	<u>\$ 0.11</u>
Diluted	<u>\$ (0.22)</u>	<u>\$ (0.11)</u>	<u>\$ 0.05</u>	<u>\$ 0.32</u>	<u>\$ 0.10</u>
Weighted average common and potential common shares outstanding (1):					
Basic	101,358	105,858	107,346	110,754	115,396
Diluted	101,358	105,858	112,530	117,960	120,776

	Year Ended December 31,				
	1997	1998	1999	2000	2001
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 85,402	\$ 69,908	\$ 70,368	\$ 88,845	\$153,242
Total assets	108,377	97,737	112,328	170,886	386,760
Accumulated deficit	(69,179)	(80,908)	(75,268)	(37,105)	(24,470)
Total stockholder's equity	96,187	85,807	94,991	147,046	350,308

(1) See Note 2 in the notes to the consolidated financial statements for an explanation of the computation of basic and diluted per share data.

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

### Overview

The Company designs, develops, manufactures and markets a sample preparation system for medical diagnostic applications. The ThinPrep System consists of the Thin Prep Processor, and related disposable reagents, filters and other supplies. The Company has marketed the ThinPrep System for use in non-gynecological testing applications since 1991. On May 20, 1996, the Company received PMA approval from the FDA to market the ThinPrep System for cervical cancer screening as a replacement for the conventional Pap smear method. On November 6, 1996, the FDA cleared expanded product labeling for the ThinPrep System to include the claim that the ThinPrep System is significantly more effective in detecting low grade and more severe lesions than the conventional Pap smear method in a variety of patient populations. The expanded labeling also indicates that the specimen quality using the ThinPrep System is significantly improved over that of the conventional Pap smear method. On February 25, 1997, the FDA approved the Company's supplemental PMA application for use of a combination of an endocervical brush and spatula sampling devices, which is a commonly used method of collecting samples for conventional Pap smears.

On September 4, 1997, the FDA approved the Company's supplemental PMA application for the testing for HPV directly from a single vial of patient specimen collected in ThinPrep solution using the Hybrid Capture HPV DNA Assay of Digene. In March 1999, the FDA approved the use of Digene's Hybrid Capture II HPV DNA Assay from a single vial of patient specimen collected in ThinPrep solution.

The Company commenced the full-scale commercial launch of the ThinPrep System for cervical cancer screening in the United States in 1997 and in selected international markets in 1998. In May 2000, the FDA approved the ThinPrep® 3000 Processor, the Company's next-generation processor for automated sample preparation. In August 2001, the FDA approved the Company's PMA Supplement Application for the inclusion of data describing the detection of High-Grade Squamous Intraepithelial Lesions (HSIL) with the ThinPrep Pap Test. In December 2001, the Company submitted a supplemental PMA application to the FDA to allow for testing for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoea (NG) directly from the ThinPrep Pap Test vial using RDC's COBAS Amplicor™ automated system. In January 2002, the Company submitted a PMA Application to the FDA for the ThinPrep Imaging System to aid in cervical cancer screening.

Prior to 2000, the Company incurred substantial losses, principally from expenses associated with obtaining FDA approval of the Company's ThinPrep System for cervical cancer screening, engineering and development efforts related to the ThinPrep 2000 Processor, ThinPrep 3000 Processor, and ThinPrep Imaging System, expansion of the Company's manufacturing facilities, and the establishment of a marketing and sales organization. The Company may experience losses in the future as it expands its domestic and international marketing and sales activities and continues its product development efforts. The operating results of the Company have fluctuated significantly in the past on an annual and a quarterly basis. The Company expects that its operating results may fluctuate significantly from quarter to quarter in the future depending on a number of factors, including the extent to which the Company's products continue to gain market acceptance, the rate and

size of expenditures incurred as the Company expands its domestic and establishes its international sales and distribution networks, the timing and level of reimbursement for the Company's products by third-party payors, and other factors, many of which are outside the Company's control.

The Company occupies a 97,000 square foot facility in Boxborough, Massachusetts. The Company has installed automated customized equipment for the high-volume manufacture of disposable filters for use in connection with the ThinPrep System. In January 2000, the Company acquired approximately 2.7 acres of land and facilities of Acu-Pak, a contract packager in Londonderry, New Hampshire that was manufacturing, filling vials containing and distributing the Company's solutions for all of its ThinPrep line of products, for approximately \$6.0 million in cash. The Company accounted for the acquisition as a purchase.

In November 2001, as part of its acquisition of Pro Duct, a manufacturer of medical devices in Menlo Park, California, the Company entered into a lease for a facility consisting of approximately 35,000 square feet. The lease of this facility terminates on April 30, 2003. The Company has subleased approximately 17,000 square feet of office space in Menlo Park, California to a third party for eighteen months ending April 30, 2003. In connection with the acquisition, the Company has committed to a plan to abandon the leased facilities. The Company has accrued approximately \$787,000 for the abandonment of the leased facility, representing the present value of future minimum lease payments less estimated sub-lease receipts.

The cost per ThinPrep® Pap Test™, plus a laboratory mark-up, is generally billed by laboratories to third-party payors and results in a higher amount for the ThinPrep Pap Test than the current billing for conventional Pap tests. Successful sales of the ThinPrep System for cervical cancer screening in the United States and other countries will depend on the availability of adequate reimbursement from third-party payors such as private insurance plans, managed care organizations and Medicare and Medicaid. Although many health insurance companies have added the ThinPrep Pap Test to their coverage, there can be no assurance that third-party payors will provide or continue to provide such coverage, that reimbursement levels will be adequate or that health care providers or clinical laboratories will use the ThinPrep System for cervical cancer screening in lieu of the conventional Pap smear method.

Since January 1, 1998, the Company's laboratory customers have been able to request reimbursement for the ThinPrep Pap Test from health insurance companies and the Center for Medicare and Medicaid Services ("CMS") using a newly assigned Common Procedure Technology ("CPT") code specifically for liquid-based monolayer cervical cell specimen preparation. CPT codes are assigned, maintained and revised by the CPT Editorial Board, which is administered by the American Medical Association, and are used in the submission of claims to third-party payors for reimbursement for medical services. CMS has established a national fee of \$28 for the CPT codes describing the ThinPrep Pap Test. This reimbursement level is nearly double the level of reimbursement for the conventional Pap smear.

The Company's direct sales force is actively working with current laboratory customers and health insurance companies to facilitate reimbursement under the CPT code. As of December 31, 2001, based on information provided to the Company, the Company believes that all of the 367 health insurance companies which announced coverage of the ThinPrep Pap Test have implemented the new CPT code and have established a reimbursement amount. There are approximately six hundred managed care organizations and other third party payors in the United States. There can be no assurance, however, that reimbursement levels under the new CPT code will be adequate.

The Company expects to continue its significant expenditures for sales and marketing activities of the ThinPrep System for cervical cancer screening and the ductal lavage device acquired from Pro Duct in 2002.

In January 2000, the Company entered into a supply and co-marketing agreement with Quest to market the ThinPrep Pap Test as Quest's exclusive liquid-based cervical cancer screening methodology.

In October 2000, the Company entered into an agreement with RDC, exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for chlamydia and gonorrhea using RDC's COBAS® AMPLICOR® CT/NG Test directly from the ThinPrep collection vial. The companies also intend to explore the potential for collaborating on a portfolio of additional screening and diagnostic tests based on the companies' respective technologies.

In January 2001, the Company entered into an agreement with Digene, exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for human papillomavirus (HPV) using Digene's Hybrid Capture® II HPV DNA Assay directly from the ThinPrep collection vial. The companies expect that the co-promotion program will initially focus on promoting Digene's HPV DNA test, using the residual material in ThinPrep collection vials, as the optimal patient management strategy for borderline cytology results.

The Company expects to increase its expenditures in 2002 for research and development to fund development of the ductal lavage device acquired from Pro Duct, as well as follow-on products and additional applications of ThinPrep technology.

#### Recent Acquisitions

In October 2001, the Company announced that it had entered into a definitive merger agreement to acquire all of the outstanding securities of Pro Duct, a privately held company that has developed a ductal lavage device to enhance the evaluation of risk for breast cancer. In November 2001, the Company completed its acquisition of Pro Duct by means of a merger of Pro Duct with and into Cytoc Health Corporation, a wholly-owned subsidiary of Cytoc Corporation. The Company intends to market the ductal lavage device as the ThinPrep Breast Test™, subject to required regulatory approvals.

On February 19, 2002, the Company announced that it had signed a definitive merger agreement to acquire all of the outstanding securities of Digene in an exchange offer transaction. If the acquisition is consummated, the Company will issue approximately 23 million shares of common stock and pay \$76.9 million in cash for the outstanding equity of Digene (calculated on a fully diluted basis using the treasury stock method). The Company also will assume all options to acquire Digene common stock that are outstanding as of the closing of the merger that follows the tender offer. The acquisition is structured as a tax-free reorganization.

The closing of the exchange offer is subject to the tender of over 50 percent of Digene's outstanding securities, regulatory approval, and other customary closing conditions. Although the Company expects that its acquisition of Digene will close during the second quarter of 2002, the Company may not be able to complete the acquisition during the second quarter, or at all.

#### In Process Research and Development

The Company incurred in-process research and development charges totaling approximately \$56.0 million in 2001. These charges related to the acquisition of Pro Duct. The Company determined these valuations giving explicit consideration to the Securities and Exchange Commission's views on purchased in-process research and development as set forth in its September 9, 1998 letter to the American Institute of Certified Public Accountants SEC Regulations Committee (the "AICPA Letter"). These valuations were further based upon appraisals prepared by an independent appraiser experienced in evaluating in-process research and development. A description of the valuation methodology and assumptions used in those valuations are set forth below.

As part of the purchase price allocation, all intangible assets that are a part of the merger were identified and valued. It was determined that technology assets had value. As a result of this identification and valuation process, the Company allocated approximately \$56.0 million of the purchase price to in-process research and development projects. This allocation represented the estimated fair value based on risk-adjusted cash flows related to the incomplete research and development related primarily to three projects. At the date of acquisition,

the development of these projects had not yet reached technology feasibility and the research and development in progress had no alternative future uses. Accordingly, these costs were charged to expense as of the date of the merger.

In making purchase price allocation, management considered present value calculations of income, an analysis of project accomplishments and remaining outstanding items, an assessment of overall contributions, as well as project risks. The value assigned to purchased in-process research and development was determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting net cash flows from the projects, and discounting the net cash flows to their present value. The revenue projection used to value the in-process research and development was based on 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. The resulting net cash flows from such projects are based on management's estimates of cost of sales, operating expenses, and income taxes from such projects.

Aggregate revenues for Pro Duct were estimated to grow at a compounded annual growth rate of approximately 111% for the five years following the acquisition, assuming the successful completion and market acceptance of the major research and development programs.

The rates utilized to discount the net cash flows to their present value were based on estimated weighted average cost of capital calculations. Due to the nature of the forecast and the risks associated with the development projects, a range of discount rates of 25% to 30% were used for the in-process research and development. The discount rate utilized was higher than the Company's weighted average cost of capital due to the inherent uncertainties surrounding the successful development of the purchased in-process technology, the useful life of such technology, the profitability levels of such technology, and the uncertainty of technological advances that are unknown at this time.

Due to the very short lapse of time from the date of acquisition to December 31, 2001 the Company has not revised any estimates or assumptions made above. However, the Company is constantly reviewing the allocation of its research and development resources to respond to the ever changing market and technology developments, as well as developments of internally developed and acquired evolving technology portfolio.

As of December 31, 2001 expenditures incurred and estimates to complete the acquired in-process projects are consistent with the Company's expectations. If the Company is not successful in implementing its projects, it may be unable to realize the value assigned to this in-process technology. In addition, the value of the other acquired intangible assets associated with this technology may also become impaired.

#### Critical Accounting Policies

In December 2001, the SEC requested that all registrants list their most "critical accounting policies" in MD&A. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Management believes that the following accounting policies fit this definition:

*Revenue Recognition.* The Company's revenue recognition policy is significant because revenue is a key component of the Company's results of operations. The Company follows very specific and detailed guidelines in measuring revenue; however, certain judgments affect the application of its revenue policy. For example, revenue is not recognized from sales transactions unless the collection of the resulting receivable is reasonably assured. The Company assesses collection based on a number of factors, including past transaction history with the customer and the credit-worthiness of the customer. If it is determined that the collection of a fee is not reasonably assured, the fee is deferred and revenue is recognized at the time collection becomes reasonably assured, which is generally upon receipt of cash. Revenue results are difficult to predict, and any shortfall in

revenue or delay in recognizing revenue could cause our operating results to vary significantly from quarter to quarter.

*Valuation of Long-Lived Assets and Deferred Taxes.* The Company assesses the impairment of identifiable intangibles, long-lived assets and goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If it is determined that the carrying value of intangible, long-lived assets and goodwill might not be recoverable based upon the existence of one or more indicators of impairment, the Company would measure any impairment based on a projected discounted cash flow method. No such impairment charges have been recorded to date. In 2002, Statement of Financial Accounting Standards ("SFAS") No. 142 "Goodwill and Other Intangible Assets" became effective and as a result, the Company will cease to amortize goodwill. In lieu of amortization, the Company is required to perform an initial impairment of our goodwill in 2002 and an annual impairment review thereafter. The Company currently does not expect to record an impairment charge upon completion of the initial impairment review. However, there can be no assurance that at the time the review is completed a material impairment charge will not be recorded. Carrying value of the Company's net deferred tax assets assumes that the Company will be able to generate sufficient future taxable income in certain tax jurisdictions, based on estimates and assumptions. If these estimates, and related assumptions change in the future, the Company may be required to record additional valuation allowances against its deferred tax assets resulting in additional income tax expense in the Company's consolidated statement of operations.

*Accounts Receivable Reserve.* The Company performs ongoing credit evaluations of its customers and adjusts credit limits based upon payment history and the customer's credit worthiness, as determined by its review of their current credit information. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses based upon our historical experience and any specific customer collection issues that have been identified. While such credit losses have historically been within the Company's expectations and the provisions established, it cannot guarantee that it will continue to experience the same credit loss rates that it has in the past.

The above list is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result. See the Company's audited consolidated financial statements and notes thereto which begin on page F-1 which contain accounting policies and other disclosures required by generally accepted accounting policies.

## **Results of Operations**

### *Years Ended December 31, 2001 and December 31, 2000*

Net sales increased to \$221.0 million in 2001 from \$142.1 million in 2000, an increase of 55.6%. This increase was primarily due to increased sales of the Company's ThinPrep Pap Test for cervical cancer screening in the United States. Gross profit increased to \$180.8 million in 2001 from \$117.5 million in 2000, an increase of 53.9%, however the gross margin decreased as a percentage of net sales to 81.8% in 2001 from 82.7% in 2000. Management attributes the decrease in gross margin in 2001 primarily to customer mix.

Total operating expenses increased to \$151.1 million in 2001 from \$83.2 million in 2000, an increase of 81.6%. Excluding a one-time charge of \$56.0 million for in-process research and development related to the Company's acquisition of Pro Duct in November 2001, total operating expenses increased 14.3%. Research and development costs increased to \$19.0 million in 2001, excluding a one-time charge of \$56.0 million for in-process research and development related to the Pro Duct acquisition, from \$14.2 million in 2000, an increase of 33.9%, primarily as a result of engineering costs, additional personnel expenses and clinical trial costs associated with the Company's ThinPrep Imaging System development activities. Sales and marketing costs increased to

\$59.2 million in 2001 from \$55.2 million in 2000, an increase of 7.2%. The increase primarily relates to personnel costs, including commissions, increased regional meetings and marketing programs. The Company expects that sales and marketing costs will increase in succeeding quarters as a result of increased expenditure for personnel, marketing programs and commissions expense, all of which increase with sales. General and administrative costs increased to \$17.0 million in 2001 from \$13.9 million in 2000, an increase of 22.5%, primarily due to a combination of increased personnel costs and professional fees, including those related to business development activities of Cytoc Healthcare Ventures, LLC, partially offset by decreased litigation expenses. Interest income increased to \$5.4 million in 2001 from \$4.7 million in 2000, an increase of 14.3%, due to an increase in the average cash balance available for investment. The Company recorded \$3.1 million in 2001 as other income relating to the settlement of certain litigation. The Company also recorded approximately \$16,000 and \$192,000 in foreign currency transaction losses in 2000 and 2001, respectively.

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

Net sales increased to \$142.1 million in 2000 from \$81.1 million in 1999, an increase of 75.2%. This increase was primarily due to increased sales of the Company's ThinPrep Pap Test for cervical cancer screening in the United States. Gross profit increased to \$117.5 million in 2000 from \$65.3 million in 1999, an increase of 80.0%, and the gross margin increased to 82.7% in 2000 from 80.5% in 1999. Management attributes the increase in gross margin in 2000 primarily to increased sales of the higher gross margin ThinPrep Pap Test in the United States compared to domestic sales of the ThinPrep Processor or international sales of either tests or processors.

Total operating expenses increased to \$83.2 million in 2000 from \$64.2 million in 1999, an increase of 29.7%. Research and development costs increased to \$14.2 million in 2000 from \$13.4 million in 1999, an increase of 6.0%, primarily as a result of engineering costs and additional personnel expenses associated with the Company's ThinPrep Imaging System development activities. Sales and marketing costs increased to \$55.2 million in 2000 from \$44.0 million in 1999, an increase of 25.3%. The increase primarily related to personnel costs in domestic sales and marketing, including commissions, travel and meetings expense, marketing medical education programs in the United States and the expansion of international sales and marketing. The Company expects that sales and marketing costs will increase in succeeding quarters as a result of increased expenditure for personnel, marketing programs and commissions expense, all of which increase with sales. General and administrative costs increased to \$13.9 million in 2000 from \$6.8 million in 1999, an increase of 105.1%, due to increased legal expenses associated with litigation and increased personnel costs and professional fees. During the third quarter of 1999, the Company revised its estimate and reversed approximately \$700,000 in legal expenses which had been accrued for certain litigation which was favorably settled during the second quarter of 1999, with all related efforts and costs completed in the third quarter. Excluding the reversal, general and administrative expenses would have increased 85.8%. Interest income increased to \$4.7 million in 2000 from \$3.8 million in 1999, an increase of 24.9%, due to an increase in the average cash balance available for investment and higher average interest rates. The Company recorded \$1.1 million in 1999 as other income relating to the settlement of certain litigation. The Company also recorded approximately \$292,000 and \$16,000 in foreign currency transaction losses in 1999 and 2000, respectively.

**Liquidity and Capital Resources**

Since inception, the Company's expenses have significantly exceeded its revenue, resulting in an accumulated deficit of \$24.5 million as of December 31, 2001. Although the Company generated cash of \$31.9 million and \$10.3 million in 2000 and 2001, respectively, the Company had previously funded its operations primarily through the private placement and public sale of equity securities and exercise of stock options and warrants aggregating \$194.6 million, net of offering expenses. At December 31, 2001, the Company had cash, cash equivalents and short-term investments of \$153.2 million. Cash provided by the Company's operations was \$1.7 million, \$25.9 million and \$91.7 million during 1999, 2000 and 2001, respectively, primarily as a result of net income generated in each period, partially offset by increases in working capital for each year. In 2001, cash provided by operations was primarily the result of net income, as adjusted for non cash items

including deferred taxes and the charge related to acquired in process research and development, partially offset by an increase in net working capital items, especially an increase in accounts receivable. Net accounts receivable increased by \$10.1 million to approximately \$50.3 million during 2001 as a result of significant sales growth in 2001. Net inventories decreased approximately \$0.4 million from December 31, 2000 to December 31, 2001 due primarily to improved inventory management and production control.

The Company's investing activities used cash of approximately \$9.2 million, \$2.5 million and \$90.2 million during 1999, 2000 and 2001, respectively. The Company's investing activities included capital expenditures for the years ended December 31, 1999, 2000 and 2001 of \$3.8 million, \$10.8 million and \$9.3 million, respectively. The Company's investing activities utilized cash of approximately \$4.5 million for the purchase of short-term investments in 1999 and generated cash of approximately \$13.5 million from the sale of short-term investments during 2000. The Company's investing activities also utilized \$25.8 million in cash to acquire Pro Duct and \$54.0 million to purchase short-term investments during 2001.

The Company's financing activities generated cash of approximately \$3.6 million, \$9.1 million and \$9.8 million in 1999, 2000 and 2001, respectively. The Company's financing activities consisted primarily of proceeds from the exercise of common stock options and warrants of approximately \$3.3 million, \$8.4 million and \$8.7 million during 1999, 2000 and 2001, respectively.

The Company leases its facilities under non-cancelable operating leases which have expiration dates ranging from 2002 through 2011. At December 31, 2001, future minimum annual lease payments amount to \$7.4 million under these leases.

The Company's future liquidity and capital requirements will depend upon numerous factors, including the resources required to further develop its marketing and sales capabilities, both domestic and international, the extent to which such activities generate market acceptance and demand for the ThinPrep System for cervical cancer screening and additional applications of its ThinPrep technology, including the ductal lavage device acquired from Pro Duct. The Company's liquidity and capital requirements will also depend upon the progress of the Company's research and development programs to develop follow-on products including the ThinPrep Imaging System and the ductal lavage device acquired from Pro Duct, the receipt of and the time required to obtain regulatory clearances and approvals, and the resources the Company devotes to developing, manufacturing and marketing its products. In addition, the Company's capital requirements will depend on the extent of potential liabilities, if any, and costs associated with any future litigation. There can be no assurance that the Company will not require additional financing or will not in the future seek to raise additional funds through bank facilities, debt or equity offerings or other sources of capital. Additional funding may not be available when needed or on terms acceptable to the Company, which would have a material adverse effect on the Company's business, financial condition and results of operations.

#### Income Taxes

The Company has net operating loss and research and development tax credit carryforwards for federal income tax purposes of approximately \$45.2 million and \$7.8 million, respectively, at December 31, 2001 that will expire at various dates through the year 2020, if not utilized. The Company has an Alternative Minimum Tax ("AMT") tax credit carryforward for federal income tax purposes of approximately \$1.0 million.

The net operating loss and research and development tax credit carryforwards are subject to review by the Internal Revenue Service. Ownership changes, as defined in the Internal Revenue Code, may limit the amount of these tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The Company's effective tax rate was 1.1% and 2.1% in 1999 and 2000, respectively, which was less than the then current combined federal and state statutory rates. This difference was caused primarily by utilization of the Company's net operating loss carryforwards. The Company's effective tax rate for 2001 was 66.5% which was higher than the then current combined federal and state statutory rate. This was caused primarily by the non deductible in process research and development charge related to the Pro Duct acquisition, partially offset by utilization of the Company's net operating loss carryforwards.

#### **Quantitative and Qualitative Disclosures About Market Risk**

*Derivative Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments.* The Company does not participate in derivative financial instruments, other financial instruments for which the fair value disclosure would be required under SFAS No. 107, or derivative commodity instruments. All of the Company's investments are in short-term, investment-grade commercial paper, corporate bonds and U.S. Government and agency securities that are carried at fair value on the Company's books. Accordingly, the Company has no quantitative information concerning the market risk of participating in such investments.

*Primary Market Risk Exposures.* The Company's primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. The Company's investment portfolio of cash equivalents is subject to interest rate fluctuations, but the Company believes this risk is immaterial due to the short-term nature of these investments. The Company's business outside the United States is conducted in local currency transactions. The Company has no foreign exchange contracts, option contracts, or other foreign hedging arrangements. However, the Company estimates that any market risk associated with its foreign operations is not significant and is unlikely to have a material adverse effect on the Company's business, financial condition or results of operations.

#### **Certain Factors Which May Affect Future Results**

The forward looking statements in this Form 10-K are made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended. The Company's operating results and financial condition have varied and may in the future vary significantly depending on a number of factors.

Statements in this Form 10-K which are not strictly historical statements, including, without limitation, statements regarding management's expectations for future growth and plans and objectives for future management and operations, domestic and international marketing and sales plans, product plans and performance, potential savings to the healthcare system, management's assessment of market factors, statements concerning the integration of Pro Duct, statements concerning the acquisition of Digene, as well as statements regarding the strategy and plans of the Company, constitute forward-looking statements that involve risks and uncertainties. The following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon the Company's business, financial condition, and results of operations.

The following discussion of the Company's risk factors should be read in conjunction with the consolidated financial statements and related notes included herein. Because of these and other factors, past financial performance should not be considered an indication of future performance.

*We depend principally on the sale of a single product.*

To date, we have derived most of our revenues from sales of our ThinPrep 2000 Processor, related instruments, filters, and other supplies for use in gynecological and non-gynecological testing applications. If we

are unable to successfully develop and commercialize other products, our business, sales and profits will be materially impaired. Although we have begun marketing our next-generation ThinPrep 3000 Processor and we have submitted a PMA application to the FDA for approval to sell our ThinPrep Imaging System, neither product has generated significant revenues yet. We cannot guarantee that the development of our ThinPrep Imaging System will be successfully completed, or that we will obtain necessary regulatory approval to market the ThinPrep Imaging System in the United States or in other countries. We also cannot guarantee that we will be able to obtain adequate reimbursement from insurance companies and other third party payors for the ductal lavage device for the detection of breast cancer that we obtained in our acquisition of Pro Duct, or that we will otherwise be able to generate significant revenue from sales of the Pro Duct device. We may be required to obtain FDA approval and secure adequate reimbursement from insurance companies and other third party payors for any other new products that we are able to develop or acquire, and we may not be able to do so.

*We cannot guarantee we will obtain necessary regulatory approvals for our products.*

If we do not obtain all necessary regulatory approvals for any new products we are able to successfully develop or acquire, our ability to generate sales from new product offerings will materially suffer. The governments of the United States and other countries extensively regulate the manufacture and sale of medical diagnostic devices intended for commercial use. For example, United States commercial sales of medical diagnostic devices require FDA approval before selling may commence. Obtaining FDA and other required regulatory approvals can be time-consuming, expensive and uncertain. Regulatory approval frequently requires several years from the commencement of clinical trials to the receipt of regulatory approval. After any approvals, we remain subject to pervasive regulation and inspection for compliance with regulatory requirements. In January 2002, the Company submitted a PMA Application to the FDA for the ThinPrep Imaging System to aid in cervical cancer screening. We do not know whether the FDA will approve these products for commercial use. We may also need to obtain FDA approval for any other new products we are able to develop or acquire, and we cannot guarantee that we will be able to do so.

*Our success depends on the market acceptance of our products and their cost.*

Our success and growth depends primarily on market acceptance of our ThinPrep System, including any follow-on applications of ThinPrep technology for cervical cancer screening and any other new products we are able to successfully develop or acquire, including the ductal lavage device we obtained in our acquisition of Pro Duct. The laboratory cost of using the ThinPrep System for cervical cancer screening is higher than that of a conventional Pap smear. Due in part to increased competitive pressures in the healthcare industry to reduce costs, our ability to gain market acceptance of the ThinPrep System and follow-on products depends on our ability to demonstrate that the higher cost of using the ThinPrep System is offset by a reduction in costs often associated with conventional Pap smears, such as inaccurate diagnoses and the need for repeat Pap tests. In particular, for all of our products, including our ThinPrep System products and the Pro Duct ductal lavage device, we need to convince healthcare providers, insurance companies and other third party payors, and clinical laboratories of the clinical benefits and cost-effectiveness of our products.

*We have limited marketing and sales experience, which could cause our sales to suffer.*

In order to effectively market our products and increase our sales and profits, we will need to continue to increase our marketing and sales capabilities both within the United States and in foreign countries. We received clearance from the FDA to market our ThinPrep System for cervical cancer screening in May 1996, and initiated full-scale marketing and sales efforts for the ThinPrep System in the United States beginning in the first quarter of 1997. We currently utilize both direct sales and strategic marketing relationships with large clinical laboratories and health care companies to market our products in the United States. We cannot guarantee that our direct sales force or strategic marketing relationships will succeed in promoting the ThinPrep System, or any other products we are able to develop or acquire, to healthcare providers, third-party payors or clinical

laboratories, or that we will sufficiently establish additional marketing and sales channels. While we are currently evaluating marketing and sales channels outside of the United States, including contract sales organizations, distributors and marketing partners, we have established very limited foreign sales channels. We may not be able to establish successful marketing and distribution agreements or other channels for sales outside of the United States. We also cannot guarantee that we will be able to recruit and retain skilled marketing, sales, service and support personnel for our domestic and foreign sales and marketing efforts.

*Our sales are dependent on third-party reimbursement.*

We cannot sell our ThinPrep System for cervical cancer screening in the United States and other countries unless we are able to secure adequate reimbursement from third-party payors such as private insurance plans, managed care organizations, and Medicare and Medicaid. Although a number of managed care organizations in the United States have added the ThinPrep Pap Test to their coverage, we cannot guarantee that reimbursement will increase or continue to be available, or that reimbursement levels will be adequate to enable healthcare providers and clinical laboratories in the United States and other countries to use the ThinPrep System for cervical cancer screening instead of the conventional Pap smear method. We also will be required to secure adequate reimbursement for any new products we develop or obtain, including the Pro Duct ductal lavage device, and we may not be able to do so successfully.

*We have a limited number of customers and a lengthy sales process to generate new customers, which may adversely impact our sales.*

We are dependent on a relatively small number of large clinical laboratory customers in the United States for a significant portion of our sales of the ThinPrep System, and our business may materially suffer if we are unable to increase sales to our existing customers and establish new customers both within and outside the United States. Due in part to a trend toward consolidation of clinical laboratories in recent years and the relative size of the largest United States laboratories, it is likely that a significant portion of ThinPrep System sales will continue to be concentrated among a relatively small number of large clinical laboratories. To generate demand for the ThinPrep Pap Test among clinical laboratories, we must educate physicians and healthcare providers about the clinical benefits and cost-effectiveness of the ThinPrep System. We also need to demonstrate the availability of adequate levels of reimbursement for the ThinPrep Pap Test. This process requires a lengthy sales effort, which makes it difficult and expensive for us to obtain new customers.

*We have a limited operating history.*

We have a limited operating history, which may make it difficult for you to evaluate our business and prospects. We received initial pre-market approval from the FDA to market our ThinPrep System as a replacement for the conventional pap smear in May 1996 and commenced full-scale commercial launch in the United States in 1997. Since that time, we have focused on follow-on product development, obtaining additional regulatory approvals, expanding our manufacturing capabilities, and establishing our marketing and sales capabilities and channels in the United States and internationally. Our future revenues and profitability depend significantly on our ability to successfully market and sell the ThinPrep System and any follow-on products both within and outside of the United States. Due in part to our limited operating history, you should not rely on our historical results of operations as an indication of our prospects for future revenues and profitability.

*We may engage in acquisitions that may harm our operating results, dilute our stockholders, divert management's attention from other important business concerns, and potentially create other difficulties for us.*

On November 30, 2001, we completed the acquisition of Pro Duct, a privately-held company that has developed an FDA approved ductal lavage device designed to improve the evaluation of risk for breast cancer. On February 19, 2002, we signed a definitive agreement to acquire Digene by means of a stock and cash tender offer. We may in the future pursue additional acquisitions that we believe could provide us with new technologies, products or service offerings, or enable us to obtain other competitive advantages.

Acquisitions by us, including our acquisition of Pro Duct and our acquisition of Digene (if we are able to complete it), may involve some or all of the following financial risks:

- use of significant amounts of cash;
- potential dilutive issuances of equity securities;
- incurrence of debt or amortization expenses related to certain intangible assets; and
- future impairment charges related to diminished fair value of businesses acquired as compared to their net book value.

Such acquisitions also may involve numerous other risks, including:

- diversion of management's attention from other business concerns;
- difficulties associated with assimilating and integrating the personnel, operations and technologies of the acquired companies;
- failure to retain key personnel;
- loss of key customers, customer dissatisfaction or performance problems with the acquired company;
- the costs associated with the integration of acquired operations; and
- assumption of unknown liabilities.

We may not be successful in overcoming the risks described above or any other problems associated with our acquisition of Pro Duct or any other acquisitions. Any of these risks and problems could materially harm our business, prospects, and financial condition. Additionally, we cannot guarantee that Pro Duct or any other companies we acquire will achieve anticipated revenues and operating results.

*Our success depends on our ability to manage growth effectively.*

The scope of our operations and facilities, the number of our employees and the geographic area of our operations are growing rapidly, including as a result of acquisitions. If we are not able to manage our growth effectively, our business and financial condition will materially suffer. Our growth may significantly strain our managerial, operational and financial resources and systems. To manage our growth effectively, we will have to continue to implement and improve additional management and financial systems and controls, and to expand, train and manage our employee base. These difficulties will be increased if we are able to complete our acquisition of Digene.

*We have intense competition from other companies.*

We face direct competition from a number of publicly-traded and privately-held companies, including at least one other manufacturer of a thin-layer slide preparation system. The development, FDA approval and commercial marketing of competitive systems for cervical cancer screening could have a material adverse effect on our business and financial condition. Many of our existing and potential competitors have substantially greater financial, marketing, sales, distribution and technical resources than we do, as well as more experience in research and development, clinical trials, regulatory matters, manufacturing and marketing.

*Our quarterly operating results may vary.*

We expect that our operating results will fluctuate significantly in the future. Our quarterly results will depend on a number of factors, many of which are outside our control. These factors include:

- the extent to which our products gain market acceptance;

- the rate and size of expenditures incurred as we expand our domestic and establish our international sales and distribution networks;
- the timing of approvals of the ThinPrep System and any other new products, including the Pro Duct Health ductal lavage device, for reimbursement by third-party payors;
- the timing and size of sales;
- the likelihood and timing of FDA approval of PMA supplements related to the ThinPrep System and any other new products;
- the timing and size of expenditures incurred in the research and development of new products; and
- the introduction and market acceptance of competing products or technologies.

*We currently have limited foreign sales capabilities and cannot guarantee success in foreign markets.*

Although we commenced sales of our ThinPrep System in countries outside the United States in 1998, only a small percentage of our sales to date have been outside of the United States. If we fail to increase our revenues from sales outside of the United States, our business and financial condition may suffer materially. While we continue to evaluate possibilities for new foreign marketing and sales channels, including contract sales organizations, distributors and marketing partners, our current foreign sales channels are very limited. We cannot guarantee that we will successfully develop foreign sales channels or capabilities that will enable us to generate significant revenue from sales outside of the United States. Even if we are able to establish foreign sales capabilities, we may not be able to obtain required third-party reimbursements and regulatory approvals in foreign countries.

*We are uncertain if additional applications of our ThinPrep System will be successful.*

In late 2000 and early 2001, we entered into separate co-promotion agreements for the co-promotion of RDC's COBAS® AMPLICOR® CT/NG test for the detection of chlamydia and gonorrhea and Digene's Hybrid Capture® II HPV DNA Assay for the detection of the human papillomavirus. Each test utilizes our ThinPrep collection vial. We intend to continue to evaluate additional uses of our ThinPrep technology in testing for the presence of other types of cancers and sexually transmitted diseases. We have not yet determined which of these additional applications we will seek to develop, commercialize or promote, alone or with other companies. We cannot guarantee that our agreements with RDC or Digene will be successful, or that we will be able to successfully promote, commercialize or develop additional uses of our technology in connection with testing for other cancers or sexually transmitted diseases.

*We are highly dependent on key personnel.*

We are highly dependent on the principal members of our management and scientific staff. Loss of our key personnel would likely impede achievement of our research and development, operational, or strategic objectives. To be successful, we must retain key employees and attract additional qualified employees.

*Our success depends on our ability to protect our intellectual property rights.*

We rely on a combination of patents, trade secrets, copyrights, trademarks and confidentiality agreements to protect our proprietary technology, rights and know-how. We also are the exclusive licensee of certain patented technology for use in the field of cytology related to the fluid pumping system used in the ThinPrep System. If we fail to protect, defend and maintain our intellectual property rights, or if we are subject to a third party claim of infringement, our business and financial condition will materially suffer.

*Our reliance on sole source suppliers could harm our business.*

We currently obtain certain key components of the ThinPrep System, including our proprietary filter material, from single sources. We have been increasing our inventory of these components in an effort to reduce

this risk. If we are unable to obtain sufficient quantities of these components at reasonable prices and in a timely manner, we will not be able to manufacture our products on a timely and cost-competitive basis, which would materially and adversely affect our business and financial condition.

*Impact of Euro Conversion.* On January 1, 1999, 11 of the 15 member countries of the European Economic and Monetary Union established fixed conversion rates between their existing sovereign currencies and the Euro, and adopted the Euro as their common legal currency. The Euro is currently being traded on currency exchanges and is available for non-cash transactions. For a three-year transition period, both the Euro and each participating country's sovereign currency will remain legal currency. After June 30, 2002, the Euro will be the sole legal tender for the participating countries.

A significant amount of uncertainty exists as to the interpretation of certain Euro regulations and the effect that the Euro will have on the marketplace, including its impact on currency exchange rate risk, pricing, competition, contracts, information systems and taxation. During 2001, the Company derived less than 1% of its revenues from sales of the ThinPrep System to customers in countries which have converted to the Euro. The Company is currently evaluating Euro-related issues and the impact that the introduction of the Euro may have on the Company's business and results of operations. The Company expects to take appropriate actions based on the results of its evaluation. The Company has not yet determined the costs of addressing Euro-related issues, but does not expect such costs to be material. Because the Company's evaluation of Euro-related issues is at an early stage and is ongoing, however, there can be no assurance that such issues and their related costs will not have a material adverse effect on the Company's business, financial condition and results of operations.

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

The information required by this item may be found on pages F-1 through F-24 of this Form 10-K.

**Item 9. Disagreements with Accountants on Accounting and Financial Disclosure**

There have been no changes in or disagreements with accountants on accounting or financial disclosure matters in the last two fiscal years.

### PART III

#### Item 10. Directors and Executive Officers of the Registrant

The information required under this item may be found under the sections captioned "Election of Directors", "Occupations of Directors and Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's Proxy Statement (the "2002 Proxy Statement"), which will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2001, and is incorporated herein by reference.

#### Item 11. Executive Compensation

The information required under this item may be found under the section captioned "Compensation and Other Information concerning Directors and Officers" in the 2002 Proxy Statement, and is incorporated herein by reference.

#### Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required under this item may be found under the section captioned "Securities Ownership of Certain Beneficial Owners and Management" in the 2002 Proxy Statement, and is incorporated herein by reference.

#### Item 13. Certain Relationships and Related Transactions

The information required under this item may be found under the caption "Certain Relationships and Related Transactions" in the 2002 Proxy Statement, and is incorporated herein by reference.

## PART IV

### Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a)(1) *Consolidated Financial Statements.*

For a list of the consolidated financial information included herein, see Index on page F-1.

(a)(2) *Financial Statement Schedules.*

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Consolidated Financial Statements or notes thereto.

(a)(3) *List of Exhibits.*

The following exhibits are filed as part of and incorporated by reference into, this Annual Report on Form 10-K:

Exhibit Number	Description
2.1(11)	Agreement and Plan of Merger, dated October 17, 2001, by and among Cytoc Corporation, Pro Duct Health, Inc., and Cytoc Health Corporation.
2.2(12)	Amendment to Agreement and Plan of Merger, dated as of November 30, 2001, by and among Cytoc Corporation, Pro Duct Health Inc., and Cytoc Health Corporation.
2.3(13)	Agreement and Plan of Merger, dated as of February 19, 2002, by and among Cytoc Corporation, Digene Corporation, and Cruiser, Inc.
3.1(2)	Third Amended and Restated Certificate of Incorporation of the Company.
3.2(2)	Amended and Restated By-Laws of the Company.
3.3(9)	Certificate of Amendment of Third Amended and Restated Certificate of Incorporation.
4.1(1)	Speciman certificate representing the Common Stock.
4.2(3)	Rights Agreement, dated as of August 27, 1997, between Cytoc Corporation and BankBoston, N.A (the "Rights Agreement") which includes as Exhibit A the Form of Certificate of Designations, as Exhibit B the Form of Rights Certificate, and as Exhibit C the Summary of Rights to Purchase Preferred Stock.
4.3(4)	Amendment No. 1 to Rights Agreement, dated as of June 22, 1998, between Cytoc Corporation and BankBoston, N.A., amending the Rights Agreement.
10.1(1)*	1988 Stock Plan.
10.2(1)*	1989 Stock Plan.
10.3(1)*	1995 Stock Plan.
10.4(10)*	Amended and Restated 1995 Non-Employee Director Stock Option Plan.
10.5(14)*	1995 Employee Stock Purchase Plan, as amended.
10.6(1)#	License Agreement between the Company and DEKA Products Limited Partnership dated March 22, 1993.
10.7(1)	Form of Indemnification Agreement.
10.8(1)	Lease Agreement between the Company and BFA Realty Partnership, L.P. d/b/a BFA, Limited Partnership of February 1996.
10.9(5)	Amendment No.1 to Lease Agreement dated as of February 1996 between the Company and BFA Realty Partnership, L.P. d/b/a BFA, Limited Partnership.
10.10(6)#	Co-Promotion Agreement dated as of May 27, 1997 by and between Mead Johnson & Company and the Company.
10.11(7)#	Amendment No. 1 to Co-Promotion Agreement dated as of May 27, 1997 by and between Mead Johnson & Company and the Company.

Exhibit  
Number

Description

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|------------|--|
| 10.12(8)*  | Cytc Corporation Director Deferred Compensation Plan.  |
| 10.13(15)* | 2001 Non-Employee Director Stock Plan.   |
| 10.14(16)* | Pro Duct Health, Inc. 1998 Stock Plan.   |
| 21.1**     | List of Subsidiaries of the Company.   |
| 23.1**     | Consent of Arthur Andersen LLP.  |
| 24.1**     | Power of Attorney (see signature page hereto).   |
| 99.1(12)   | Escrow Agreement, dated as of November 30, 2001, by and among Cytc Corporation, the Pro Duct Health, Inc. stockholder representative, and JPMorgan Chase Bank.                                 |
| 99.2(11)   | Form of Registration Rights Agreement by and among Cytc Corporation and holders of the capital stock of Pro Duct Health, Inc.  |
| 99.3(11)   | Voting Agreement, dated as of October 17, 2001, by and among Cytc Corporation and certain principal stockholders of Pro Duct Health, Inc.  |
| 99.4(13)   | Stockholders Agreement dated as of February 19, 2002 by and among Cytc Corporation, Cruiser, Inc. and executive officers, directors, and certain principal stockholders of Digene Corporation. |
| 99.5(13)   | Transaction Option Agreement, dated as of February 19, 2002 by and between Cytc Corporation and Digene Corporation.  |
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- (1) Incorporated herein by reference to the exhibits to the Company's Registration Statement on Form S-1 (File No. 333-00300).
  - (2) Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (File No. 333-19367).
  - (3) Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed August 29, 1997 (File No. 000-27558).
  - (4) Incorporated herein by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q, filed August 13, 1998 (File No. 000-27558).
  - (5) Incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, filed March 31, 1998 (File No. 000-27558).
  - (6) Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed August 8, 1997 (File No. 000-27558).
  - (7) Incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, filed March 31, 1998 (File No. 000-27558).
  - (8) Incorporated herein by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K, filed March 31, 1999 (File No. 000-27558).
  - (9) Incorporated herein by reference to Exhibits 3, 4 to the Company's Quarterly Report on Form 10-Q, filed August 14, 2000 (File No. 000-27558).
  - (10) Incorporated herein by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q, filed August 14, 2000 (File No. 000-27558).
  - (11) Incorporated herein by reference to the Exhibits to the Company's Current Report on Form 8-K, filed October 19, 2001 (File No. 000-27558).
  - (12) Incorporated herein by reference to the Exhibits to the Company's Current Report on Form 8-K, filed December 14, 2001 (File No. 000-27558).
  - (13) Incorporated herein by reference to the Exhibits to the Company's Current Report on Form 8-K, filed February 20, 2002 (File No. 000-27558).
  - (14) Incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-00300) and Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed August 8, 2001 (File No. 000-27558).

- (15) Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed August 8, 2001 (File No. 000-27558).
- (16) Incorporated herein by reference to Exhibit 4 to the Company's Registration Statement on Form S-8, filed December 17, 2001 (File No. 333-75292).

\* Indicates a management contract or any compensatory plan, contract or arrangement.

\*\* Filed herewith.

# Confidential treatment granted as to certain portions.

(b) *Reports On Form 8-K*

There were two reports on Form 8-K filed by the Company for the quarter ended December 31, 2001.

On October 19, 2001, the Company filed a current report on Form 8-K reporting Item 5—Other Events—to disclose the Company's execution of a definitive Agreement and Plan of Merger to acquire Pro Duct Health, Inc., and filing as exhibits to such Form 8-K under Item 7—Financial Statements, Pro Forma Financial Statements and Exhibits—the related Agreement and Plan of Merger, Voting Agreement and Form of Registration Rights Agreement and a Press Release announcing the execution of the merger agreement.

On December 14, 2001, the Company filed a current report on Form 8-K reporting Item 2—Acquisition or Disposition of Assets—to disclose the consummation of the Company's acquisition of Pro Duct Health, Inc., and filing as exhibits to such Form 8-K under Item 7—Financial Statements, Pro Forma Financial Statements and Exhibits—an amendment to the Pro Duct Health Agreement and Plan of Merger, an Escrow Agreement related to the Pro Duct acquisition and a Press Release announcing the consummation of the acquisition.

Subsequent 8-K filings

On February 5, 2002, the Company filed a current report on Form 8-K reporting Item 5—Other Events—to disclose Press Release announcing the Company's establishment of an open market stock repurchase program.

On February 12, 2002, the Company filed a current report on Form 8-K/A reporting Amendment No. 1 to its Current Report on Form 8-K dated December 14, 2001, solely to file the financial statements of Pro Duct Health, Inc. required by Item 7(a) of Form 8-K and the pro forma financial information required by Item 7(b) of Form 8-K.

On February 20, 2002, the Company filed a current report on Form 8-K reporting Item 5—Other Events—to disclose the Company's execution of a definitive Agreement and Plan of Merger to acquire Digene Corporation, and filing as to such Form 8-K under Item 7—Financial Statements, Pro Forma Financial Statements and Exhibits—the related Agreement and Plan of Merger, Stockholders Agreement and Transaction Option Agreement, and a Joint Press Release announcing the execution of the merger agreement.

(c) *Exhibits*

The Company hereby files as part of this Annual Report on Form 10-K the exhibits listed in Item 14(a)(3) set forth above. Exhibits which are incorporated herein by reference may be inspected and copied at the public reference facilities maintained by the SEC at Room 1024, Washington, D.C. 20549, and at the SEC's regional offices located at Seven World Trade Center, Suite 1300, New York, New York 10048, and at Citicorp Center, 500 West Madison Street, Suite 1400 Chicago, Illinois 60611-2511. Copies of such material may be obtained by mail from the Public Reference Section of the SEC at Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. The SEC also maintains a Website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at the address "http://www.sec.gov".

## SIGNATURES

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

## CYTYC CORPORATION

Date: March 1, 2002

By: /s/ PATRICK J. SULLIVAN

Chief Executive Officer Vice Chairman and  
Chairman elect of the Board of Directors

## POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Cytac Corporation, hereby severally constitute and appoint Patrick J. Sullivan and Robert L. Bowen, and each of them singly, our true and lawful attorneys, with full power to both of them and each of them singly, to sign for us and in our names in the capacities indicated below, any amendments to this Report on Form 10-K, and generally to do all things in our names and on our behalf in such capacities to enable Cytac Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities and Exchange Commission.

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

<u>Signature</u>	<u>Title(s)</u>	<u>Date</u>
<u>/s/ PATRICK J. SULLIVAN</u> Patrick J. Sullivan	Chief Executive Officer (Principal Executive Officer), Vice Chairman and Chairman elect of the Board of Directors	March 1, 2002
<u>/s/ ROBERT L. BOWEN</u> Robert L. Bowen	Vice President, and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2002
<u>/s/ WALTER E. BOOMER</u> Walter E. Boomer	Director	March 1, 2002
<u>/s/ MARC C. BRESLAWSKY</u> Marc C. Breslawsky	Director	March 1, 2002
<u>/s/ SALLY W. CRAWFORD</u> Sally W. Crawford	Director	March 1, 2002

<u>Signature</u>	<u>Title(s)</u>	<u>Date</u>
<u>/s/ WILLIAM G. LITTLE</u> William G. Little	Director	March 1, 2002
<u>/s/ WILLIAM H. LONGFIELD</u> William H. Longfield	Director	March 1, 2002
<u>/s/ JOSEPH B. MARTIN, M.D., Ph. D.</u> Joseph B. Martin, M.D., Ph. D.	Director	March 1, 2002
<u>/s/ C. WILLIAM MCDANIEL</u> C. William McDaniel	Vice Chairman of the Board of Directors	March 1, 2002
<u>/s/ ANNA S. RICH</u> Anna S. Richo	Director	March 1, 2002
<u>/s/ MONROE E. TROUT, M.D.</u> Monroe E. Trout, M.D.	Chairman of the Board of Directors	March 1, 2002

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CYTYC CORPORATION  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Public Accountants .....	F-2
Consolidated Balance Sheets as of December 31, 2000 and 2001 .....	F-3
Consolidated Statements of Operations for the Years Ended December 31, 1999, 2000 and 2001 .....	F-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 1999, 2000 and 2001 .....	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 1999, 2000 and 2001 .....	F-6
Notes to Consolidated Financial Statements .....	F-7

## REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Stockholders and Board of Directors of  
Cytac Corporation:

We have audited the accompanying consolidated balance sheets of Cytac Corporation (a Delaware corporation) and subsidiaries as of December 31, 2000 and 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

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

ARTHUR ANDERSEN LLP

Boston, Massachusetts  
January 21, 2002,  
(except with respect to the matter  
discussed in note 14 as to which  
the date is February 19, 2002).

**CYTYC CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share amounts)

	December 31,	
	2000	2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 61,605	\$ 71,928
Short-term investments .....	27,240	81,314
Accounts receivable, net of allowance of \$1,510 and \$1,987 at December 31, 2000 and 2001, respectively .....	40,214	50,278
Inventories .....	11,093	10,698
Prepaid expenses and other current assets .....	937	1,583
Total current assets .....	141,089	215,801
Property and equipment, net .....	21,363	26,662
Intangible assets:		
Patented technology, net of accumulated amortization of \$219 at December 31, 2001 .....	—	211
Acquired developed technology and know-how, net of accumulated amortization of \$122 at December 31, 2001 .....	—	18,878
Goodwill, net of accumulated amortization of \$444 and \$885 at December 31, 2000 and 2001, respectively .....	2,670	94,881
Total intangible assets .....	2,670	113,970
Deferred tax assets, net .....	—	23,485
Other assets, net .....	5,764	6,842
Total assets .....	\$170,886	\$386,760
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 6,043	\$ 9,325
Accrued expenses .....	15,720	24,789
Deferred revenue .....	2,077	1,501
Total current liabilities .....	23,840	35,615
Non-current liabilities .....	—	837
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred Stock, \$0.01 par value—		
Authorized—5,000,000 shares		
No shares issued or outstanding .....	—	—
Common Stock, \$0.01 par value—		
Authorized—200,000,000 shares		
Issued and outstanding—113,039,385 shares in 2000 and 121,355,344 in 2001 .....	1,130	1,214
Additional paid-in capital .....	183,653	376,092
Deferred compensation .....	—	(999)
Accumulated other comprehensive loss .....	(632)	(1,529)
Accumulated deficit .....	(37,105)	(24,470)
Total stockholders' equity .....	147,046	350,308
Total liabilities and stockholders' equity .....	\$170,886	\$386,760

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

**CYTYC CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Years Ended December 31,		
	1999	2000	2001
Net sales .....	\$ 81,100	\$142,065	\$220,993
Cost of sales .....	15,815	24,565	40,168
Gross profit .....	<u>65,285</u>	<u>117,500</u>	<u>180,825</u>
Operating expenses:			
Research and development .....	13,372	14,171	18,975
In-process research and development .....	—	—	56,000
Sales and marketing .....	44,017	55,162	59,161
General and administrative .....	6,765	13,872	16,987
Total operating expenses .....	<u>64,154</u>	<u>83,205</u>	<u>151,123</u>
Income from operations .....	<u>1,131</u>	<u>34,295</u>	<u>29,702</u>
Other income (expense):			
Interest income .....	3,790	4,734	5,412
Other income (expense) .....	849	(13)	(493)
Litigation settlement .....	—	—	3,087
Total other income, net .....	<u>4,639</u>	<u>4,721</u>	<u>8,006</u>
Income before provision for income taxes .....	5,770	39,016	37,708
Provision for income taxes .....	130	853	25,073
Net income .....	<u>\$ 5,640</u>	<u>\$ 38,163</u>	<u>\$ 12,635</u>
Net income per common and potential common share:			
Basic .....	<u>\$ 0.05</u>	<u>\$ 0.34</u>	<u>\$ 0.11</u>
Diluted .....	<u>\$ 0.05</u>	<u>\$ 0.32</u>	<u>\$ 0.10</u>
Weighted average common and potential common shares outstanding:			
Basic .....	107,346	110,754	115,396
Diluted .....	112,530	117,960	120,776

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

**CYTYC CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands, except share amounts)

	Comprehensive Income	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Compre- hensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
		Number of Shares	Value					
Balance, December 31, 1998	\$ —	106,791,570	\$1,068	\$165,541	\$ —	\$ 106	\$(80,908)	\$ 85,807
Exercise of common stock options and warrants		1,501,026	15	3,291	—	—	—	3,306
Issuance of shares under Employee Stock Purchase Plan	—	97,920	—	276	—	—	—	276
Issuance of shares under Directors' Stock Plan	—	29,118	—	121	—	—	—	121
Comprehensive income—								
Net income	\$ 5,640	—	—	—	—	—	5,640	5,640
Other comprehensive income (loss)—								
Unrealized loss on marketable securities	(150)	—	—	—	—	(150)	—	(150)
Cumulative translation adjustment	(9)	—	—	—	—	(9)	—	(9)
Comprehensive income	\$ 5,481	—	—	—	—	—	—	—
Balance, December 31, 1999		108,419,634	1,083	169,229	—	(53)	(75,268)	94,991
Exercise of common stock options	—	4,541,340	47	8,320	—	—	—	8,367
Issuance of shares under Employee Stock Purchase Plan	—	50,025	—	694	—	—	—	694
Issuance of shares under Directors' and Executive Stock Plans	—	28,386	—	241	—	—	—	241
Issuance of common stock warrant	—	—	—	5,169	—	—	—	5,169
Comprehensive income—								
Net income	\$38,163	—	—	—	—	—	38,163	38,163
Other comprehensive income (loss)—								
Unrealized gain on marketable securities	165	—	—	—	—	165	—	165
Cumulative translation adjustment	(744)	—	—	—	—	(744)	—	(744)
Comprehensive income	\$37,584	—	—	—	—	—	—	—
Balance, December 31, 2000		113,039,385	1,130	183,653	—	(632)	(37,105)	147,046
Exercise of common stock options	—	2,733,117	27	8,714	—	—	—	8,741
Issuance of common stock to non- employees for services	—	3,000	—	52	—	—	—	52
Issuance of shares under Employee Stock Purchase Plan	—	61,280	1	1,065	—	—	—	1,066
Issuance of shares under Directors' and Executive Stock Plans	—	24,162	1	392	—	—	—	393
Exercise of common stock warrant	—	494,400	5	(5)	—	—	—	—
Issuance of common stock for Pro Duct acquisition	—	5,000,000	50	140,114	—	—	—	140,164
Deferred compensation for common stock options assumed in Pro Duct acquisition	—	—	—	1,054	(1,054)	—	—	—
Amortization of deferred compensation	—	—	—	—	55	—	—	55
Tax benefit from stock options exercised	—	—	—	41,053	—	—	—	41,053
Comprehensive income—								
Net income	\$12,635	—	—	—	—	—	12,635	12,635
Other comprehensive income (loss)—								
Unrealized gain on marketable securities	98	—	—	—	—	98	—	98
Cumulative translation adjustment	(995)	—	—	—	—	(995)	—	(995)
Comprehensive income	\$11,738	—	—	—	—	—	—	—
Balance, December 31, 2001		121,355,344	\$1,214	\$376,092	\$ (999)	\$(1,529)	\$(24,470)	\$350,308

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

**CYTYC CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years Ended December 31,		
	1999	2000	2001
<b>Cash flows from operating activities:</b>			
Net income	\$ 5,640	\$ 38,163	\$ 12,635
Adjustments to reconcile net income to net cash provided by operating activities			
Depreciation and amortization	1,951	3,460	4,852
Provision for doubtful accounts	299	656	567
Amortization of warrant	—	1,465	2,499
Acquired in-process research and development	—	—	56,000
Non-cash gain from settlement of litigation	—	—	(2,712)
Compensation expense related to issuance of stock to directors, executives and non-employee awards	121	241	445
Compensation expense related to options assumed in acquisition	—	—	55
Change in deferred tax asset	—	—	(20,540)
Changes in assets and liabilities, excluding effects of acquisition—			
Accounts receivable	(10,130)	(18,050)	(10,549)
Inventories	(1,454)	(5,388)	598
Prepaid expenses and other current assets	(133)	(139)	(639)
Accounts payable	1,845	1,188	2,829
Accrued expenses	3,253	3,966	5,156
Deferred revenue	309	355	(576)
Tax benefit from exercise of options	—	—	41,053
Net cash provided by operating activities	<u>1,701</u>	<u>25,917</u>	<u>91,673</u>
<b>Cash flows from investing activities:</b>			
Acquisition of Acu-Pak, Inc., net of cash acquired	—	(5,760)	—
Acquisition of Pro Duct Health Inc., net of cash acquired	—	—	(25,791)
(Increase) decrease in other assets	(878)	651	(1,147)
Purchases of property and equipment	(3,786)	(10,813)	(9,248)
Purchases of short-term investments	(59,882)	(49,803)	(156,293)
Proceeds from sale of short-term investments	55,392	63,259	102,317
Net cash used in investing activities	<u>(9,154)</u>	<u>(2,466)</u>	<u>(90,162)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of stock options and warrants	3,306	8,367	8,741
Proceeds from issuance of shares under Employee Stock Purchase Plan	276	694	1,066
Net cash provided by financing activities	<u>3,582</u>	<u>9,061</u>	<u>9,807</u>
Effect of exchange rate changes on cash	(9)	(593)	(995)
Net (decrease) increase in cash and cash equivalents	(3,880)	31,919	10,323
Cash and cash equivalents, beginning of year	33,566	29,686	61,605
Cash and cash equivalents, end of year	<u>\$ 29,686</u>	<u>\$ 61,605</u>	<u>\$ 71,928</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for income taxes	\$ 138	\$ 442	\$ 1,866
<b>Supplemental disclosure of non-cash items:</b>			
Unrealized holding (loss) gain on short-term investments	\$ (150)	\$ 165	\$ 98
Issuance and exercise of common stock warrant to Quest Diagnostics, Inc.	\$ —	\$ 5,169	\$ 5
Non-cash portion of gain on settlement of litigation	\$ —	\$ —	\$ —
Issuance of shares under director's and executive stock plans	\$ 121	\$ 241	\$ 393
Issuance of common stock to non-employees for services	\$ —	\$ —	\$ 52
<b>In connection with the acquisition of Acu-Pak, Inc and Pro Duct Health Inc., in 2000 and 2001, respectively, the following non-cash transactions occurred:</b>			
Fair value of assets acquired	\$ —	\$ 7,173	\$ 115,158
In-process research and development	—	—	56,000
Fair value of common shares issued and stock options assumed	—	—	(140,164)
Cash paid for acquisition and acquisition costs	—	(6,179)	(25,791)
Liabilities assumed	<u>\$ —</u>	<u>\$ 994</u>	<u>\$ 5,203</u>

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

**CYTYC CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2001

**(1) The Company**

Cytec Corporation and subsidiaries (the "Company") design, develop, manufacture and market sample preparation systems for medical diagnostic applications. The Company's principal product, the ThinPrep System, is an automated system for the preparation of non-gynecological samples and cervical specimens on microscope slides.

In 1991, the Company commenced commercial sales of ThinPrep Processors, reagents, filters and related supplies for non-gynecological diagnostic applications to clinical laboratories and hospitals. On May 20, 1996, the Company received clearance from the U.S. Food and Drug Administration to market the ThinPrep System for cervical cancer screening.

In November 2001, the Company acquired Pro Duct, a privately held company that developed a ductal lavage device to enhance the evaluation of risk for breast cancer. The Company intends to market the ductal lavage device as the ThinPrep Breast Test™, subject to required regulatory approvals.

In the past, the Company incurred substantial losses, principally from expenses associated with obtaining FDA approval of the ThinPrep System, engineering and development efforts related to the ThinPrep System, expansion of the Company's manufacturing facilities and the establishment of a sales and administrative organization. The Company continues to be subject to certain risks common to medical device companies in similar stages of development, including dependence on a single product, extensive government regulation, uncertainty of market acceptance, and uncertainty of future profitability.

**(2) Summary of Significant Accounting Policies**

The accompanying consolidated financial statements reflect the application of certain significant accounting policies, as discussed below and elsewhere in the notes to consolidated financial statements. The Company considers its most critical accounting policies, defined as those which are both important to the portrayal of the Company's financial condition and results and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. The Company has identified its critical accounting policies to be those related to revenue recognition, valuation of long-lived assets and deferred taxes and accounts receivable reserve. The preparation of these consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures 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.

*(a) Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries: Cytec Europe, S.A. (a Swiss corporation) (including its wholly-owned subsidiaries Cytec Swiss, S.A. and Cytec SARL, whose wholly-owned subsidiaries are Cytec Italia, S.R.L. and Cytec France, S.A.R.L.), Cytec (Australia) Pty, Limited (an Australian corporation), Cytec Canada, Ltd. (a Canadian corporation), Cytec (UK) Limited (a United Kingdom corporation), Cytec Germany GmbH (a German company), Cytec Securities Corporation (a Massachusetts securities corporation), Cytec Interim Inc., (a Delaware corporation), Cytec International, Inc., (a Delaware corporation), Cytec Health Corporation (a Delaware corporation), Cruiser, Inc. (a Delaware corporation) and Cytec Healthcare Ventures, LLC (a Delaware limited liability corporation). All intercompany amounts have been eliminated in consolidation.

**CYTYC CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2001**

*(b) Revenue Recognition*

The Company follows the provisions of Staff Accounting Bulletin No. 101 (SAB 101), *Revenue Recognition*. Accordingly, the Company recognizes product revenue upon shipment, provided that there is persuasive evidence of an arrangement, there are no uncertainties regarding acceptance, the sales price is fixed or determinable, collection of the resulting receivable is probable and only perfunctory Company obligations included in the arrangement remain to be completed. Deferred revenue represents amounts relating to deferred interest recorded in connection with sales-type finance leases with customers and amounts related to product billed for which revenue has not been recognized. The adoption of SAB 101 in 2000 did not have a material impact on the Company's results of operations.

*(c) Cash and Cash Equivalents*

Cash equivalents consist of money market mutual funds, commercial paper and U.S. Government securities with original maturities, at date of purchase, of three months or less.

*(d) Short-term Investments*

The Company follows the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The Company has classified its marketable securities as available-for-sale and records them at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive income in stockholders' equity (see Note 2 (I)).

At December 31, 2001, the Company's available-for-sale securities had contractual maturities that expire at various dates through December 2002. The fair value of available-for-sale securities was determined based on quoted market prices at the reporting date for those securities. Available-for-sale securities are shown in the consolidated financial statements at fair market value. At December 31, 2001 and 2000, the amortized cost basis, aggregate fair value, gross unrealized holding gains (losses) and average months to maturity by major security type are as follows:

	<u>Amortized Cost</u>	<u>Gross Unrealized Holding Gains (Losses)</u>	<u>Fair Value</u>
		(in thousands)	
<b>December 31, 2001</b>			
Available-for-sale securities			
U.S. Government and Agency securities (average maturity of 3.9 months)	\$55,711	\$ 44	\$55,755
Corporate Bonds (average maturity of 5.0 months) . . . . .	22,601	68	22,669
Commercial Paper (average maturity of 1.2 months) . . . . .	<u>2,889</u>	<u>1</u>	<u>2,890</u>
	<u>\$81,201</u>	<u>\$ 113</u>	<u>\$81,314</u>
<b>December 31, 2000</b>			
Available-for-sale securities			
U.S. Government and Agency securities (average maturity of 8.2 months)	\$14,535	\$ 21	\$14,556
Corporate Bonds (average maturity of 9.4 months) . . . . .	1,691	6	1,697
Commercial Paper (average maturity of 2.5 months) . . . . .	<u>10,999</u>	<u>(12)</u>	<u>10,987</u>
	<u>\$27,225</u>	<u>\$ 15</u>	<u>\$27,240</u>

**CYTYC CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**December 31, 2001**

*(e) Concentration of Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk are principally cash, cash equivalents, short-term investments and accounts receivable. The Company places its investments in highly rated financial institutions. Concentration of credit risk with respect to accounts receivable is limited to certain customers to whom the Company makes substantial sales. To reduce risk, the Company routinely assesses the financial strength of its customers and, as a consequence, believes that its accounts receivable credit risk exposure is limited. The Company maintains an allowance for potential credit losses but historically has not experienced any significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. In 1999, 2000 and 2001 the accounts receivable balance from one customer represented approximately 13%, 15% and 20% of the Company's accounts receivable portfolio.

*(f) Dependence on Single Source Suppliers*

Certain key components of the ThinPrep System, including its proprietary filter material, are currently provided to the Company by single sources. In the event that the Company is unable to obtain sufficient quantities of such components on commercially reasonable terms, or in a timely manner, the Company would not be able to manufacture its products on a timely and cost-competitive basis, which would have a material adverse effect on the Company's business, consolidated financial position and results of operations.

*(g) Depreciation and Amortization*

The Company provides for depreciation and amortization by charges to operations, on a straight-line basis, in amounts estimated to allocate the cost of the assets over their estimated useful lives as follows:

<u>Asset Classification</u>	<u>Estimated Useful Life</u>
Production equipment .....	3-7 Years
Research equipment .....	3-7 Years
Furniture, fixtures and computer equipment .....	2-7 Years
Building .....	40 Years
Leasehold improvements .....	Life of lease

*(h) Other Assets*

Other assets consist primarily of the value of Tripath common shares, (see Note 11), long-term lease receivables from the sale of ThinPrep Processors and the unamortized balance of the value assigned to a warrant (see Note 2(r)).

*(i) Research and Development Costs*

The Company charges research and development costs to operations as incurred.

*(j) Net Income Per Common Share*

The Company follows the provisions of SFAS No. 128, *Earnings Per Share*, which requires companies to report both basic and diluted per share data, for all periods for which a statement of operations is presented. Basic net income per share is computed by dividing net income by the weighted average number of common shares

CYTYC CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares and potential common shares from outstanding stock options and warrants. Potential common shares are calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company's outstanding stock options and warrant. The following table provides a reconciliation of the denominators used in calculating basic and diluted net income per share for the years ended December 31, 1999, 2000 and 2001.

	Years Ended December 31,		
	1999	2000	2001
		(in thousands)	
Basic weighted average common shares outstanding . . . . .	107,346	110,754	115,396
Dilutive effect of assumed exercise of stock options and warrant . .	5,184	7,206	5,380
Weighted average common shares outstanding assuming dilution .	<u>112,530</u>	<u>117,960</u>	<u>120,776</u>

Diluted weighted average shares outstanding excludes 86,183, 317,006 and 244,079 potential common shares from stock options and warrant outstanding for the years ended December 31, 1999, 2000 and 2001, respectively, as their effect would be anti-dilutive.

In accordance with the provisions of SFAS No. 128, and as a result of the January 2000 and March 2001 stock splits, the Company has retroactively restated prior years' earnings per share (see Note 9).

(k) *Post-Retirement and Post-Employment Benefits*

The Company has no obligations for post-retirement or post-employment benefits.

(l) *Reporting Comprehensive Income*

SFAS No. 130 *Reporting Comprehensive Income* establishes standards for the reporting and display of comprehensive income and its components in the consolidated financial statements. Comprehensive income is the total of net income and all other non owner changes in equity including such items as unrealized holding gains (losses) on securities classified as available-for-sale, foreign currency translation adjustments and minimum pension liability adjustments. The Company has chosen to disclose comprehensive income in the accompanying consolidated statements of stockholders' equity.

The components of accumulated other comprehensive income (loss) are as follows:

	Year ended December 31,		
	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Available-for-sale Securities	Accumulated Other Comprehensive Income (Loss)
		(in thousands)	
Balance as of December 31, 1998 . . . . .	\$ 106	—	\$ 106
Current period change . . . . .	(9)	\$(150)	(159)
Balance as of December 31, 1999 . . . . .	97	(150)	(53)
Current period change . . . . .	(744)	165	(579)
Balance as of December 31, 2000 . . . . .	(647)	15	(632)
Current period change . . . . .	(995)	98	(897)
Balance as of December 31, 2001 . . . . .	<u>\$(1,642)</u>	<u>\$ 113</u>	<u>\$(1,529)</u>

CYTYC CORPORATION  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

(m) *Segment and Enterprise-Wide Reporting*

SFAS No. 131 *Disclosures About Segments of an Enterprise and Related Information* requires certain financial and supplementary information to be disclosed on an annual and interim basis for each reportable operating segment of an enterprise, as defined. The Company derives substantially all of its operating revenue from the sale and support of one group of similar products and services. Accordingly, based on the criteria set forth in SFAS No. 131, the Company currently operates in one segment, medical diagnostic equipment.

SFAS No. 131 also requires that certain enterprise-wide disclosures be made related to products and services, geographic areas and significant customers. Primarily all of the Company's assets are located within the United States. During 1999, 2000 and 2001, the Company derived its sales from the following countries (as a percentage of net sales):

	Years Ended		
	1999	2000	2001
United States .....	92%	92%	93%
Other .....	8%	8%	7%
	100%	100%	100%

In 1999, 2000 and 2001, sales to one customer represented approximately 11%, 19%, and 20% respectively, of net sales.

(n) *Long-lived assets*

In accordance with SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, the Company continually evaluates whether events or circumstances have occurred that indicate that the carrying value of these assets may be impaired. The Company believes there has been no significant impairment of its long-lived assets as of each of the balance sheet dates presented.

(o) *Translation of Foreign Currencies*

The accounts of the Company's foreign subsidiaries are translated in accordance with SFAS No. 52, *Foreign Currency Translation*. Accordingly, assets and liabilities of the Company's foreign subsidiaries are translated at the rates of exchange in effect at year-end. Revenues and expenses are translated using exchange rates in effect during the year. Prior to 1999, the functional currency of these subsidiaries was determined to be the U.S. dollar. As a result, foreign currency translation for all years prior to 1999 have been included in the accompanying consolidated statements of operations. However, in 1999, due to the growth in the cash flows of the subsidiaries and other factors, the Company determined that the functional currency of its subsidiaries should be the local currency. As a result, gains and losses from foreign currency translation are credited or charged to cumulative translation adjustment included in stockholders' equity in accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets. The Company realized net foreign currency transaction losses of approximately \$292,000, \$16,000, and \$192,000 in 1999, 2000 and 2001, respectively.

(p) *Recent Accounting Pronouncements*

In June 1998, the Financial Accounting Standards Board ("FASB") issued SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. This statement requires companies to record derivatives on the

## CYTYC CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting. SFAS No. 133, as amended by SFAS No. 137 and SFAS No. 138, was effective for the Company's year ending December 31, 2001. The adoption of this statement did not have a significant impact on the Company, its consolidated financial position or results from operations.

In July 2001, FASB issued SFAS No. 141, *Business Combinations*, and SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for using the purchase method of accounting. SFAS No. 142 discusses how intangible assets that are acquired should be accounted for in financial statements upon their acquisition and also how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. Beginning on January 1, 2002, with the adoption of SFAS No. 142, goodwill and certain purchased intangibles deemed to have indefinite lives will no longer be subject to amortization over their estimated useful life. Rather, the goodwill and certain purchased intangibles will be subject to an annual assessment for impairment based on fair value. The provisions of SFAS No. 142 are required to be applied starting with fiscal years beginning after December 15, 2001. The Company expects this will reduce annual amortization expense by approximately \$450,000. Management is currently evaluating the impact that this statement will have on the Company's financial statements in reviewing goodwill for impairment when applying the fair value based test.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which supercedes SFAS No. 121. SFAS No. 144 further refines the requirements of SFAS No. 121 that companies (1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (2) measure an impairment loss as the difference between the carrying amount and fair value of the asset. In addition, SFAS No. 144 provides guidance on accounting and disclosure issues surrounding long-lived assets to be disposed of by sale. The Company does not expect adoption of this statement to have a material impact on its financial position or results of operations.

#### (q) *Fair Value of Financial Instruments*

The estimated fair market values of the Company's financial instruments, which include marketable securities, accounts receivable and accounts payable approximate their carrying values due to the short-term nature of these instruments. The Company's financial instruments also include investment in sales type leases. These leases have fixed rates of interest and will be subject to fluctuations in fair value during their terms. As of December 31, 2001, the fair value of these leases approximate their carrying value based on underlying market conditions.

#### (r) *Agreement with Quest Diagnostics, Inc.*

In January 2000, the Company entered into a supply and co-marketing agreement with Quest to market the ThinPrep Pap Test as Quest's exclusive liquid-based cervical cancer screening methodology. As partial consideration for the exclusive nature of the relationship, Cytyc issued Quest a warrant to purchase 900,000 shares of common stock at an exercise price of \$10.14 per share. The Company calculated the fair value of the warrant to be approximately \$5.2 million and is amortizing such amount as a reduction in revenue over the three-year term of the agreement. The unamortized balance of approximately \$1,205,000 related to this warrant is recorded as a component of other assets in the accompanying balance sheet. The warrant was exercised in full on June 6, 2001 on a net issuance basis and the Company issued Quest 494,400 shares of the Company's common stock.

CYTYC CORPORATION  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)  
December 31, 2001

(3) Acquisitions

(a) *Acquisition of Acu-Pak, Inc.*

On January 3, 2000, the Company acquired Acu-Pak, a contract packager in Londonderry, New Hampshire, that was manufacturing, filling vials containing and distributing all of the Company's solutions for its ThinPrep line of products. In connection with the acquisition, the Company paid approximately \$6.0 million in cash, of which approximately \$2.5 million was allocated to land and building, approximately \$0.4 million to equipment, and approximately \$3.1 million to goodwill. The Company accounted for the acquisition as a purchase. Pro forma information has not been presented herein because of immateriality.

(b) *Acquisition of ProDuct Health, Inc.*

On November 30, 2001, the Company completed its acquisition of Pro Duct, by means of a merger ("the Merger") of Pro Duct with and into Cytac Health Corporation, pursuant to an Agreement and Plan of Merger dated as of October 17, 2001, as amended, (the "Merger Agreement"). Pro Duct is focused on the development and commercialization of an approach to enhance the evaluation of risk for breast cancer.

Upon the effective time of the Merger on November 30, 2001, the Company issued an aggregate of approximately 5.0 million shares of the Company's common stock, par value \$0.01 per share, and \$38,500,000 in cash in exchange for all of the outstanding capital stock, vested options and warrants of Pro Duct.

Certain shares of the Company's common stock payable to the former Pro Duct securityholders totaling approximately 489,075 shares and cash of approximately \$3,850,000 have been deposited with an escrow agent pursuant to the Merger Agreement and an Escrow Agreement dated as of November 30, 2001. The escrowed shares and cash will be used to indemnify the Company against losses, if any, resulting from breaches of the representations, warranties and covenants made by Pro Duct in the Merger Agreement or for certain intellectual property matters. The escrowed shares and cash that are not needed to cover outstanding claims made by the Company will be released on December 6, 2002.

The aggregate purchase price for Pro Duct was approximately \$183,898,000 of which \$38,500,000 was paid in cash, approximately \$137,650,000 was related to the value of approximately 5.0 million shares of the Company's common stock, approximately \$5,234,000 was for acquisition related fees and expenses and approximately \$2,514,000 was related to the fair value of approximately 105,000 unvested Pro Duct stock options. The Pro Duct Merger has been accounted for as a purchase in accordance with SFAS No. 141, and accordingly, the results of operations of Pro Duct have been included in the accompanying consolidated statement of operations from the date of the acquisition. In accordance with SFAS 141, the purchase price has been allocated to the assets and liabilities of Pro Duct based on their fair value.

As part of the purchase price allocation, all intangible assets that are a part of the merger were identified and valued. It was determined that technology assets had value. As a result of this identification and valuation process, the Company allocated approximately \$56.0 million of the purchase price to in-process research and development projects. This allocation represented the estimated fair value based on risk-adjusted cash flows related to the incomplete research and development related primarily to three projects. At the date of acquisition, the development of these projects had not yet reached technological feasibility and the research and development in progress had no alternative future uses. Accordingly, the acquired in-process research and development was charged to expense as of the date of the merger.

CYTYC CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

In making the purchase price allocation, management considered present value calculations of income, an analysis of project accomplishments and remaining outstanding items, an assessment of overall contributions, as well as project risks. The value assigned to purchased in-process research and development was determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting net cash flows from the projects, and discounting the net cash flows to their present value. The revenue projection used to value the in-process research and development was based on 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. The resulting net cash flows from such projects are based on management's estimates of cost of sales, operating expenses, and income taxes from such projects.

Aggregate revenues for Pro Duct were estimated to grow at a compounded annual growth rate of approximately 111% for the five years following the acquisition, assuming the successful completion and market acceptance of the major research and development programs.

The rates utilized to discount the net cash flows to their present value were based on estimated weighted average cost of capital calculations. Due to the nature of the forecast and the risks associated with the development projects, a range of discount rates of 25% to 30% were used for the in-process research and development. The discount rate utilized was higher than the Company's weighted average cost of capital due to the inherent uncertainties surrounding the successful development of the purchased in-process technology, the useful life of such technology, the profitability levels of such technology, and the uncertainty of technological advances that are unknown at this time.

If these projects are not successfully developed, the sales and profitability of the combined company may be adversely affected in the future periods. Additionally, the value of other acquired intangible assets may become impaired.

As a result of the identification and valuation of intangibles acquired, the Company also allocated approximately \$19,000,000 to developed technology and know-how. Developed technology represents patented and unpatented technology and know-how and is being amortized over a period of 13 years and relates to the InDuct Breast MicroCatheter, Aspirator and MicroDilator products. During fiscal 2000, Pro Duct received FDA 510(k) marketing clearance for the above mentioned products.

The excess of the purchase price over the fair value of tangible and identifiable intangible net assets of approximately \$92,653,000 as of November 30, 2001 was allocated to goodwill. In accordance with SFAS No. 142, this amount will not be systematically amortized but rather beginning in 2002, the Company will perform an annual assessment for impairment by applying a fair-value-based test.

In connection with the acquisition, the Company has committed to a plan to involuntarily terminate certain employees of Pro Duct and abandon certain lease facilities assumed. Accordingly, the Company has accrued severance and severance related expenses of approximately \$793,000 for employees to be terminated. The Company has also accrued approximately \$787,000 for the abandonment of a lease facility, primarily included in non-current liabilities in the accompanying balance sheet, representing the present value of future minimum lease payments less estimated sub-lease receipts.

**CYTYC CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2001**

The aggregate purchase price of approximately \$183,898,000 including acquisition cost was allocated as follows:

	2001 (in thousands)
Tangible net assets acquired, at fair value .....	\$ 13,272
Deferred tax asset .....	2,973
In-process research and development .....	56,000
Developed technology and know-how .....	19,000
Goodwill .....	92,653
	\$183,898

Unaudited pro forma operating results for the Company, assuming the acquisition occurred on January 1, 2000 and January 1, 2001, respectively, are presented below. These pro forma amounts for both periods presented exclude the one time charge of \$56.0 million for in process research and development related to the Pro Duct acquisition.

	Year ending December 31,	
	2000	2001
	(in thousands)	
Net sales .....	\$142,337	\$221,501
Net income .....	30,670	59,628
Net income per share		
Basic .....	0.26	0.50
Diluted .....	0.25	0.47

**(4) Allowance for Doubtful Accounts**

A summary of the allowance for doubtful accounts activity is as follows:

	December 31,		
	1999	2000	2001
	(in thousands)		
Balance, beginning of year .....	\$ 913	\$1,134	\$1,510
Amounts provided .....	299	656	567
Amounts written off .....	(78)	(280)	(90)
Balance, end of year .....	\$1,134	\$1,510	\$1,987

CYTYC CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

(5) Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market and consist of the following:

	December 31,	
	2000	2001
	(in thousands)	
Raw materials and work-in-process .....	\$ 6,353	\$ 6,377
Finished goods .....	4,740	4,321
	\$11,093	\$10,698

Work-in-process and finished goods inventories consist of materials, labor and manufacturing overhead.

(6) Property and Equipment

Property and equipment is stated at cost and consists of the following:

	December 31,	
	2000	2001
	(in thousands)	
Production equipment .....	\$ 6,688	\$ 8,651
Research equipment .....	357	454
Furniture, fixtures and computer equipment .....	8,366	11,835
Leasehold improvements .....	3,223	6,600
Land .....	579	579
Building .....	1,872	1,872
Construction-in-process .....	9,287	9,749
	30,372	39,740
Less—Accumulated depreciation and amortization .....	9,009	13,078
	\$21,363	\$26,662

CYTYC CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

(7) Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2000	2001
	(in thousands)	
Accrued compensation .....	\$ 6,313	\$ 8,334
Accrued consulting fees .....	2,991	5,244
Accrued legal fees .....	839	279
Accrued sales and VAT taxes .....	2,702	5,133
Other accruals .....	2,875	5,799
	<u>\$15,720</u>	<u>\$24,789</u>

(8) Income Taxes

The Company provides for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*. SFAS No. 109 requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement and tax base of assets and liabilities, as measured by enacted tax rates assumed to be in effect when these differences reverse.

The Company has net operating losses for federal income tax purposes of approximately \$45.2 million at December 31, 2001 that will expire at various dates beginning in 2017 and through 2020 if not utilized.

The Company has research and development tax credit carryforwards for federal income tax purposes of approximately \$7.8 million at December 31, 2001 that will expire at various dates beginning in 2002 and through 2020. In addition, the Company has an AMT tax credit carryforward for federal income tax purposes of approximately \$1.0 million.

The net operating loss and research and development tax credit carryforwards are subject to review by the Internal Revenue Service. Ownership changes, as defined in the Internal Revenue Code, may limit the amount of these tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

CYTYC CORPORATION  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

The approximate income tax effect of each type of temporary difference and carryforward is as follows:

	December 31,	
	2000	2001
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 26,671	\$16,797
Research and development and other tax credit carryforwards	5,274	7,834
AMT tax credit carryforward	—	1,019
Capitalized research and development expenses	4,073	2,742
Nondeductible accruals	754	—
Bad debt reserve	448	742
Employee benefit related reserves	398	1,410
Other temporary differences	370	209
Deferred tax asset	<u>37,988</u>	<u>30,753</u>
Deferred tax liabilities:		
Acquired know-how	—	(7,268)
Valuation allowance	(37,988)	—
Net deferred tax asset	<u>\$ —</u>	<u>\$23,485</u>

The components of the Company's tax provision are as follows:

	Year Ended December 31,		
	1999	2000	2001
	(in thousands)		
Current			
Federal	\$ —	\$ —	\$ 3,071
Foreign	—	—	41
State	130	853	1,447
Total current	<u>130</u>	<u>853</u>	<u>4,559</u>
Deferred			
Federal	—	—	20,320
State	—	—	194
Total deferred	<u>—</u>	<u>—</u>	<u>20,514</u>
Total income tax provision	<u>\$ 130</u>	<u>\$ 853</u>	<u>\$25,073</u>

CYTYC CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

A reconciliation of the federal statutory rate to the Company's effective tax rate is as follows:

	December 31,		
	1999	2000	2001
Income tax provision at federal statutory rate .....	35.0%	35.0%	35.0%
Research and development credit carryforwards .....	(0.94)	(3.30)	(2.76)
Research and development write-off related to Pro Duct acquisition ...	—	—	51.75
Changes in valuation allowance .....	(35.33)	(33.37)	(29.87)
State tax provision, net of federal benefit .....	0.98	0.33	8.99
Other .....	1.40	3.46	3.38
Effective tax rate .....	1.11%	2.12%	66.49%

(9) Stockholders' Equity

(a) Common Stock Reserved

As of December 31, 2001, the Company has reserved 22,297,088 shares of common stock for issuance as follows:

	Number of Shares
Employee and Director stock option plans .....	21,269,803
Employee stock purchase plan .....	1,027,285
	22,297,088

(b) Stock Splits

In December 1999, the Board of Directors approved a two-for-one split of the Company's common stock to be effected in the form of a 100% stock dividend. The additional shares were distributed on or about January 31, 2000 to stockholders of record on January 14, 2000. All share and per share data presented herein have been retroactively restated to give effect to this stock split.

In January 2001, the Board of Directors approved a three-for-one split of the Company's common stock to be effected in the form of a 200% stock dividend. The additional shares were distributed on or about March 2, 2001 to stockholders of record on February 16, 2001. All share and per share data presented herein have been retroactively restated to give effect to this stock split.

(c) Preferred Stock

The Company's bylaws provide for and the Board of Directors and stockholders authorized 5,000,000 shares of \$0.01 par value Preferred Stock. The Board of Directors has the authority to issue such shares in one or more series and to fix the relative rights and preferences without further vote or action by the stockholders. The Board of Directors has no present plans to issue any shares of Preferred Stock.

(d) Stockholders' Rights Plan

On August 6, 1997 the Board of Directors declared a dividend of one Preferred Stock purchase right for each outstanding share of the Company's common stock to stockholders of record at the close of business on September 5, 1997. Each right entitles the holder to purchase from the Company a unit consisting of one one-hundredth of a share of Series A Junior Participating Preferred Stock, \$0.01 par value, at a purchase price of \$110 per unit, subject to adjustment.

## CYTYC CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

#### (e) Warrants

On January 1, 2000, the Company issued to Quest a warrant to purchase up to 900,000 shares of common stock at an exercise price equal to \$10.14 per share. The warrant was issued in consideration of entering into a multi-year joint-marketing agreement. The warrant was exercised in full on June 6, 2001 using the cashless exercise feature and the Company issued Quest 494,400 shares of the Company's common stock.

#### (10) Stock Option and Employee Stock Purchase Plans

During 1995, the Board of Directors and stockholders approved the 1995 Stock Option Plan, (the "1995 Plan"). The aggregate number of shares of common stock that may be issued pursuant to the 1995 Plan is 6,000,000 plus, effective as of January 1, 1997 and each year thereafter, the excess, if any, of (i) five percent of the total number of shares of common stock issued and outstanding as of December 31 of the preceding year or then reserved for issuance upon the exercise or conversion of outstanding options, warrants or convertible securities, over (ii) the number of shares then remaining reserved and available for grant under the 1995 Plan, subject to certain adjustments, provided, however, that in no event shall more than 12,000,000 shares of common stock be issued pursuant to incentive stock options under the 1995 Plan. At December 31, 2001, 651,093 shares were available for future grant under the 1995 Plan.

In January 1998 and 1999, the Company approved for grant an aggregate of 6,000 shares of common stock to six directors (500 shares each, vesting equally each month during 1998 and 1999, respectively). In January 2000, the Company approved for grant an aggregate of 3,334 shares of common stock to seven directors (500 shares each for five directors and 417 shares each for two directors, vesting equally each month during 2000). In January 2001, the Company approved for grant an aggregate of 3,625 shares of common stock to eight directors (500 shares each for six directors, 250 for one director and 375 for one director vesting equally each month during 2001). As of December 31, 2001, options to purchase 438,696 shares of common stock were outstanding under the 1989 Stock Plan. No further options may be issued under the 1989 Stock Option Plan.

The Board of Directors and stockholders approved the 1995 Director Stock Option Plan pursuant to which options to purchase up to 1,500,000 shares of common stock were authorized for future issuance. In January 1996, the Company granted options to purchase 630,000 shares of common stock to seven directors under this plan. In January 1998 the Company granted options to purchase 270,000 common shares to three directors under the 1995 Director Option Plan. In 2000 the Company granted options to purchase 360,000 common shares to four directors under the 1995 Director Stock Option Plan. In 2001, the Company granted options to purchase 180,000 common shares to two directors under the 1995 Director Stock Option Plan. No further options may be issued under the 1995 Director Stock Option Plan. The Board of Directors and Stockholders approved the 2001 Non-Employee Director Stock Plan pursuant to which options to purchase up to 4,000,000 shares of common stock were authorized for future issuance. In 2001, the Company granted options to purchase 90,000 common shares to one director under the 2001 Non-Employee Director Stock Option Plan. At December 31, 2001, the Company had 3,910,000 shares available for future grants under the 2001 Non-Employee Director Stock Option Plan.

**CYTYC CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**December 31, 2001**

The following schedule summarizes the activity under the Company's stock option plans for the three years ended December 31, 2001.

	<u>Number of Shares</u>	<u>Range of Exercise Prices</u>	<u>Weighted Average Exercise Price per share</u>
Outstanding, December 31, 1998 .....	11,013,906	\$ 0.08–\$5.58	\$ 2.29
Granted .....	2,962,500	2.33– 7.83	3.50
Exercised .....	(1,493,856)	0.08– 4.63	2.16
Canceled .....	(736,134)	0.08– 6.01	3.01
Outstanding, December 31, 1999 .....	11,746,416	0.10– 7.83	2.56
Granted .....	6,107,025	9.90–21.63	16.02
Exercised .....	(4,541,340)	9.17–22.77	15.56
Canceled .....	(924,489)	2.33–19.33	6.61
Outstanding, December 31, 2000 .....	12,387,612	0.10–21.63	9.16
Granted .....	6,704,379	5.55–29.52	23.13
Exercised .....	(2,736,117)	0.10–21.92	3.25
Canceled .....	(636,394)	0.44–25.20	14.91
Outstanding, December 31, 2001 .....	<u>15,719,480</u>	<u>\$0.10–\$29.52</u>	<u>\$15.80</u>
Exercisable, December 31, 2001 .....	<u>4,913,064</u>	<u>\$0.10–\$26.66</u>	<u>\$ 9.22</u>
Exercisable, December 31, 2000 .....	<u>2,832,494</u>	<u>\$0.10–\$19.19</u>	<u>\$ 3.51</u>
Exercisable, December 31, 1999 .....	<u>4,357,590</u>	<u>\$0.10–\$ 6.72</u>	<u>\$ 2.02</u>

The following table summarizes information about stock options outstanding at December 31, 2001:

	Options Outstanding			Options Exercisable	
	<u>Number of Shares</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Weighted Average Exercise price per share</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per share</u>
\$ 0.10–\$ 2.96	1,758,474	5.80	\$ 1.98	1,304,113	\$ 1.78
2.98– 4.50	2,058,777	6.37	3.73	1,548,135	3.85
4.52– 12.17	1,792,181	8.16	10.65	433,601	9.57
13.17– 16.98	1,771,327	8.51	15.33	307,627	15.57
17.40– 20.75	1,906,350	9.00	20.14	482,908	20.36
20.96– 21.63	1,617,525	4.13	21.62	398,082	21.63
21.80– 21.92	1,811,492	9.08	21.92	415,577	21.92
22.40– 26.66	947,429	9.75	24.32	23,021	23.13
26.69– 26.69	1,988,825	4.99	26.69	—	—
26.71– 29.52	67,100	9.78	27.13	—	—
\$ 0.10–\$29.52	<u>15,719,480</u>	<u>7.20</u>	<u>\$15.80</u>	<u>4,913,064</u>	<u>\$ 9.22</u>

**CYTYC CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**December 31, 2001**

The weighted average fair market value of the stock options as of the date of grant for the years ended December 31, 1999, 2000 and 2001, was \$3.17, \$12.72 and \$17.37 respectively.

As a result of the acquisition of Pro Duct (Note 3(b)), the Company recorded approximately \$1,054,000 of deferred compensation as a component of stockholders' equity related to the value of unvested stock options held by employees of Pro Duct, which were exchanged for options to acquire the Company's common stock. The Company is amortizing this amount over the remaining vesting period of the stock options. During the year ended December 31, 2001, compensation expense related to these options totaled \$55,000.

In October 1995, the FASB issued SFAS No. 123, which requires the measurement of the fair value of stock-based compensation to be included in the statement of operations or disclosed in the notes to the financial statements. The Company has determined that it will continue to account for stock-based compensation for employees under APB Opinion No. 25, Accounting for Stock Issued to Employees, and elect the disclosure-only alternative under SFAS No. 123 for stock-based compensation awarded in 1999, 2000 and 2001 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The underlying assumptions used are as follows:

	December 31,		
	1999	2000	2001
Risk-free interest rate .....	5.42%	6.07%	4.49%
Expected dividend yield .....	—	—	—
Expected lives .....	5.00	5.00	5.00
Expected volatility .....	98%	105%	96%

Had compensation cost for the Company's stock option plans and Employee Stock Purchase Plan been determined consistent with SFAS No. 123, pro forma net income and net income per share would have been:

	December 31,		
	1999	2000	2001
	(in thousands, except per share data)		
Net income (loss)—			
As reported .....	\$5,640	\$38,163	\$ 12,635
Pro forma .....	164	21,450	(26,749)
Net income per share, as reported—			
Basic .....	\$ 0.05	\$ 0.34	\$ 0.11
Diluted .....	0.05	0.32	0.10
Net income (loss) per share, pro forma—			
Basic .....	\$ —	\$ 0.19	\$ (0.23)
Diluted .....	—	0.18	(0.23)

During 1995, the Board of Directors and stockholders approved the 1995 Employee Stock Purchase Plan pursuant to which 1,440,000 shares of Common Stock could be issued. Purchase price is determined by taking the lesser of 85% of the closing price on the first or last day of the period. During 2000, 50,025 shares of common stock were issued at the purchase prices of \$12.92 and \$14.67 per share. During 2001, 61,280 shares of common stock were issued at the purchase prices of \$16.00 and \$19.00 per share.

CYTYC CORPORATION  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

As of December 31, 2001, 1,027,285 shares were available for future issuance under the 1995 Employee Stock Purchase Plan.

(11) Commitments and Contingencies

(a) Lease Commitments

The Company leases its facilities under non-cancelable operating leases which have expiration dates ranging from 2002 through 2011.

At December 31, 2001, future minimum annual lease payments under these leases are as follows:

	Amount (in thousands)
2002 .....	\$2,543
2003 .....	1,909
2004 .....	1,524
2005 .....	430
2006 .....	227
Thereafter .....	801
	\$7,434

Rent expense under operating leases totaled approximately \$1,507,000, \$1,654,000 and \$1,759,000 in 1999, 2000 and 2001, respectively.

(b) Royalties

The Company is the exclusive licensee of certain patented technology used in the ThinPrep System. In consideration for this license, the Company has agreed to pay a royalty equal to 1% of net sales of the ThinPrep Processor, filter cylinder disposable products that are used with the ThinPrep System, and improvements made by the Company relating to such items. In connection with this license, royalty payments for the years ended December 31, 1999, 2000 and 2001 were approximately \$439,000, \$725,000 and \$1,114,000, respectively.

(c) Litigation

In September 1999, the Company filed suit against TriPath for patent infringement in relation to the Company's patent titled "Cell Preservative Solution". In January 2001, the Company and TriPath settled all litigation between the two companies. All claims and counterclaims against each other pending were dismissed without prejudice. The Company recorded \$3.1 million in 2001 as other income relating to the settlement of the litigation. The consideration included shares of TriPath common stock, the value of which has been recorded as a component of other assets in the accompanying balance sheet due to certain restriction on selling such shares for a period of two years.

CYTYC CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2001

(12) Employee Benefit Plan

The Company maintains an employee benefit plan under Section 401(k) of the Internal Revenue Code. The plan allows for employees to defer a portion of their salary up to the maximum allowed under IRS rules. The Company made contributions to the Plan totaling approximately \$132,000, \$430,000 and \$777,000 related to the years ended December 31, 1999, 2000 and 2001, respectively.

(13) Summary of Quarterly Data (Unaudited)

A summary of quarterly data follows (in thousands, except per share data):

	2000 Quarter Ended			
	March 31	June 30	September 30	December 31
Net sales	\$28,778	\$33,525	\$37,209	\$42,553
Gross profit	23,472	27,412	31,343	35,273
Operating profit	4,750	5,817	10,078	13,650
Net income	5,641	6,740	10,995	14,787
Net income per share:				
Basic	0.05	0.06	0.10	0.13
Diluted	0.05	0.06	0.09	0.12

	2001 Quarter Ended			
	March 31	June 30	September 30	December 31
Net sales	\$47,467	\$52,997	\$57,249	\$63,280
Gross profit	38,626	43,558	46,786	51,858
Operating profit (loss)	16,516	20,279	22,903	(29,996)
Net income (loss)	15,550	16,009	18,031	(36,955)
Net income (loss) per share:				
Basic	0.14	0.14	0.16	(0.31)
Diluted	0.13	0.13	0.15	(0.30)

(14) Subsequent Event

*Acquisition of Digene Corporation*

On February 19, 2002 the Company announced it had signed a definitive agreement to acquire Digene in a stock and cash tender offer transaction. The Company will issue 23 million shares of common stock and pay \$76.9 million in cash for all outstanding equity of Digene, representing an aggregate equity value of the transaction of \$553.7 million. The acquisition is expected to close during the second quarter of 2002, at which time the Company anticipates a charge of up to \$65.0 million related to the in-process research and development.

## Board of Directors

**Monroe Trout, M.D., Chairman**  
Chairman Emeritus  
*American Healthcare Systems*

**C. William McDaniel, Vice Chairman**  
*CWM Associates*

**Patrick J. Sullivan, Vice Chairman**  
Chairman-Elect and Chief Executive Officer  
*Cytc Corporation*

**Walter E. Boomer**  
President and Chief Executive Officer  
*Rogers Corporation*

**Marc C. Breslawsky**  
Chairman and Chief Executive Officer  
*Imagistics International Inc.*

**Sally W. Crawford**  
*Sally W. Crawford, LLC*

**William G. Little**  
Chairman and Chief Executive Officer  
*West Pharmaceutical Services, Inc.*

**William H. Longfield**  
Chairman and Chief Executive Officer  
*C.R. Bard, Inc.*

**Joseph B. Martin, M.D., Ph.D.**  
Dean of the Faculty of Medicine  
*Harvard Medical School*

**Anna S. Richo**  
Associate General Counsel  
Vice President, Law  
*Baxter Healthcare Corporation*

Cytc mourns the passing of Alfred Battaglia, who served on Cytc's board of directors from March 2000 to October 2001.

Cytc will miss his valuable advice, insight and friendship.

## Corporate Officers

**Patrick J. Sullivan**  
Vice Chairman, Chairman-Elect,  
and Chief Executive Officer

**Daniel J. Levangie**  
President and Chief Operating Officer

**Robert L. Bowen**  
Vice President, Chief Financial Officer  
and Treasurer

**A. Suzanne Meszner-Eltrich**  
Vice President, Human Resources,  
General Counsel and Secretary

## Corporate Information

### Registrar & Transfer Agent

Equiserve Trust Company  
P.O. Box 43010  
Providence, RI 02940  
Investor Relations Number: 781-575-3120  
Internet Address: <http://www.equiserve.com>

The transfer agent is responsible for maintaining Cytc's stock registry, including handling shareholder questions regarding lost stock certificates, address changes, and changes of ownership or name in which shares are held.

### Independent Accountants

Arthur Andersen LLP  
Boston, Massachusetts

### Legal Counsel

Testa, Hurwitz & Thibault, LLP  
Boston, Massachusetts

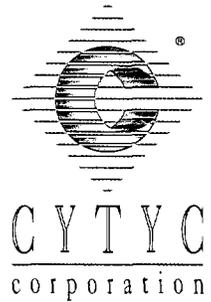
### Stock Symbol

Cytc common stock is listed on The Nasdaq Stock Market under the symbol "CYTC."

### Annual Meeting

The annual meeting of shareholders will be held Wednesday, May 22, 2002, at 9:30 a.m., at Cytc Corporation headquarters, 85 Swanson Road, Boxborough, Massachusetts.

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