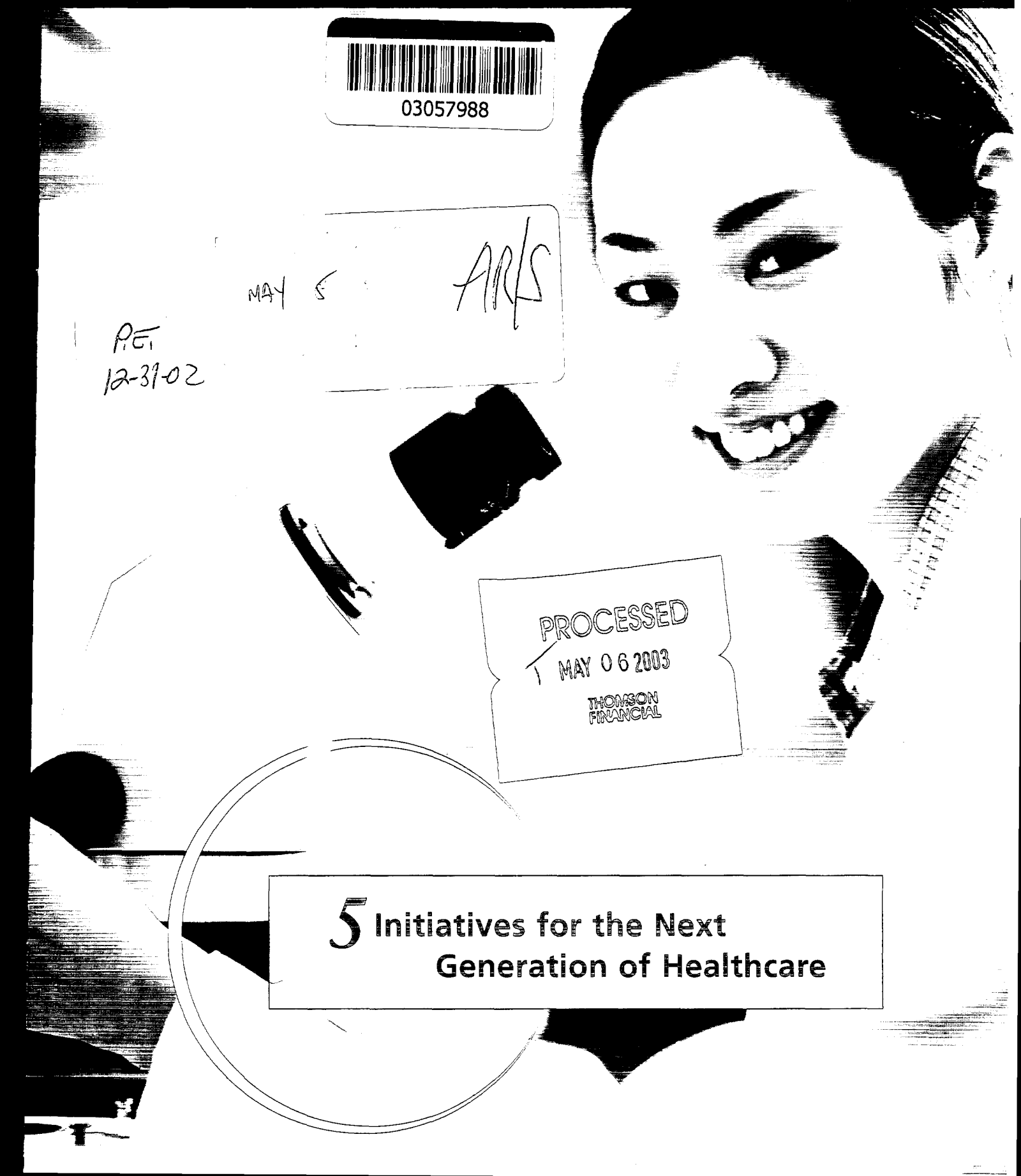
# Cytyc Corporation

2002 Annual Report



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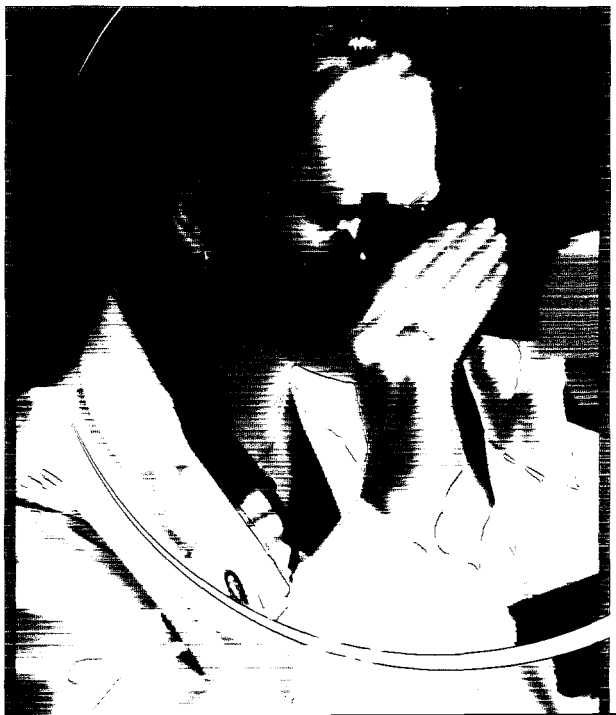
## 5 Initiatives for the Next Generation of Healthcare

# Selected Financial Data

| *(In thousands, except per share data)* | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| **Statement of Operations Data** | **2002** | **2001** | **2000** | **1999** | **1998** |
| Net sales | $236,493 | $220,993 | $142,065 | $ 81,100 | $ 44,264 |
| Gross profit | $187,871 | $180,825 | $117,500 | $ 65,285 | $ 33,053 |
| Operating expenses* | $113,325 | $151,123 | $ 83,205 | $ 64,154 | $ 52,123 |
| Operating income (loss) | $ 74,546 | $ 29,702 | $ 34,295 | $ 1,131 | $(19,070) |
| Other income, net** | $ 2,711 | $ 8,006 | $ 4,721 | $ 4,639 | $ 7,341 |
| Provision for income taxes | $ 29,363 | $ 25,073 | $ 853 | $ 130 | — |
| Net income (loss) | $ 47,894 | $ 12,635 | $ 38,163 | $ 5,640 | $(11,729) |
| Basic net income (loss) per share | $ 0.40 | $ 0.11 | $ 0.34 | $ 0.05 | $ (0.11) |
| Diluted net income (loss) per share | $ 0.39 | $ 0.10 | $ 0.32 | $ 0.05 | $ (0.11) |
| **Balance Sheet Data** | | | | | |
| Cash, cash equivalents and investment securities | $163,744 | $153,242 | $ 88,845 | $ 70,368 | $ 69,908 |
| Property and equipment, net | $ 27,281 | $ 26,662 | $ 21,363 | $ 10,660 | $ 8,825 |
| Total assets | $361,626 | $386,760 | $170,886 | $112,328 | $ 97,737 |
| Total liabilities | $ 36,898 | $ 36,452 | $ 23,840 | $ 17,337 | $ 11,930 |
| Total stockholders' equity | $324,728 | $350,308 | $147,046 | $ 94,991 | $ 85,807 |

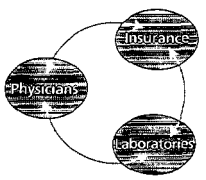
* For 2002 includes $5.7 million of expenses related to Digene merger terminated Q2 2002.
* For 2001 includes a one-time charge of $56 million for in process research and development related to Pro-Duct Health acquisition.
** For 2001 includes $3.1 million gain on litigation settlement.
** For 1998 includes $3.1 million gain on litigation settlement.



# The Next Generation of Healthcare

Cytyc Corporation designs, develops, manufactures, and markets the ThinPrep® System for use in medical diagnostic applications primarily focused on women's health. In 2002, we implemented several growth initiatives to expand market share of the ThinPrep System, which is widely used for cervical cancer screening. Specifically, we utilized the ThinPrep System platform to launch our expansion into breast cancer risk assessment with the FirstCyte™ Breast Test. In addition, we actively expanded our geographic reach to key international markets and continue to strengthen our global presence today. We are also continuing to evaluate new business opportunities to leverage our technology and distribution channel. The introduction of the ThinPrep® Imaging System later this year and opportunities for expanding molecular-based diagnostic tests are two such initiatives. We believe these initiatives will continue to positively impact women's healthcare and further Cytyc's mission to predict and prevent disease.

1 ThinPrep® Pap Test



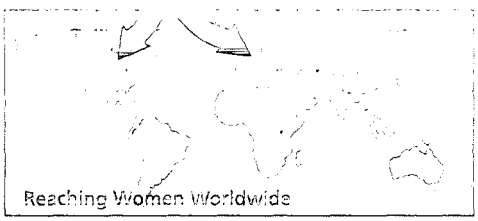

**Building Key Relationships**
An established sales and reimbursement structure for the ThinPrep Pap Test can be leveraged for the FirstCyte Breast Test.

2 FirstCyte™ Breast Test

Predict and Prevent → Diagnose and Treat

**Expanding the Medical Approach**
Detection of diseased tissues BEFORE they become invasive

3 Geographic Market Expansion




4 ThinPrep® Imaging System

Continuously improving cervical cytology imaging → Computer-assisted Cervical Cytology

5 Molecular Diagnostics

Building on platform technology → Cytyc ThinPrep® System

Platform serves as basis for numerous testing opportunities

# To Our Shareholders

The year 2002 was notable for exciting progress and solid operating and financial performance for the Company.

For the year ended December 31, 2002, we generated $236 million in revenue and net earnings of $48 million, or $0.39 per diluted share. Our balance sheet at year-end remained strong, with $164 million in cash and investments and no debt. Additionally, with the Board of Directors' authorization of a $100 million stock repurchase program in 2002, we repurchased a total of 9.6 million shares of Cytyc common stock at a cost of approximately $92.7 million. In January 2003, the Board of Directors approved an additional $50 million in the stock repurchase program for this year.

We made continued progress on expanding penetration of the **ThinPrep® Pap Test**, and at the end of 2002, we believe the ThinPrep Pap Test represented approximately 61 percent of the U.S. cervical cancer screening market. The ThinPrep Pap Test remains the only replacement to the conventional Pap smear that is significantly more effective for the detection of low-grade squamous intraepithelial (LSIL) and high-grade squamous intraepithelial (HSIL) lesions.

The ThinPrep Pap Test is further differentiated by its capability to perform additional diagnostic tests from the platform of the ThinPrep sample collection vial. We estimate that approximately 70 percent of all human papillomavirus (HPV) tests ordered by physicians are performed directly from the ThinPrep sample collection vial. During the year, the U.S. Food and Drug Administration (FDA) approved testing for *Chlamydia trachomatis* and *Neisseria gonorrhea* from the ThinPrep Pap Test sample collection vial.

By the end of 2002, we had expanded the use of the **FirstCyte Breast Test** for breast cancer risk assessment to more than 260 physicians trained to perform the procedure and more than 160 laboratories trained to interpret the samples. In addition, reimbursement coverage increased to 22 insurance companies representing approximately 29 million covered lives. With the FirstCyte Breast Test, we believe Cytyc will be instrumental in leading the shift from the current breast cancer diagnostic paradigm of "detect and treat" to "predict and prevent."

In January 2003, we expanded market reach of the FirstCyte Breast Test through maximum sales representation, and today, our entire OB/GYN sales force is working to educate primary care gynecologists about breast cancer risk assessment and patient selection. We believe this focused strategy is the key to generating physician referrals to breast cancer centers. This demand generation effort is analogous to our early experience with the launch of the ThinPrep Pap Test. Our key relationships with OB/GYNs, laboratories, and insurance companies will allow us to gain traction in this area.

We are also actively pursuing the **geographic expansion** of our business. The European cervical cancer screening market represents a significant opportunity for us, and we are encouraged by the market development in certain countries. We continue to invest in sales and marketing resources to set the foundation for international growth.

We also continue to expand the ThinPrep System. In December, we received an Approvable Letter from the FDA for the **ThinPrep Imaging System** and expect to launch this revolutionary product during the second quarter of 2003.

In addition to growing our current business, we continue to evaluate new business opportunities that would leverage our technology and distribution channel. We believe **molecular-based diagnostic tests** for cancer, particularly those for breast, ovarian, colon, bladder, prostate, and lung cancers, represent exciting growth opportunities for Cytyc over the next five years. We intend to direct fund research and make equity investments for marketing rights to exciting new diagnostic products.

Overall, I am very pleased with the progress that the Company made in 2002 and am excited about our prospects for the future. Today, through key growth initiatives, we are focusing on continued conversion to the ThinPrep Pap Test, increasing adoption of the FirstCyte Breast Test, capitalizing on the international opportunities, launching our ThinPrep Imaging System, and continuing to evaluate business development opportunities.

We believe we are building a solid foundation to support significant growth opportunities, not only in our core business but also through our new growth initiatives.

Patrick J. Sullivan

*Chairman, President, and*
*Chief Executive Officer*

## 1 ThinPrep Pap Test: Leveraging Success

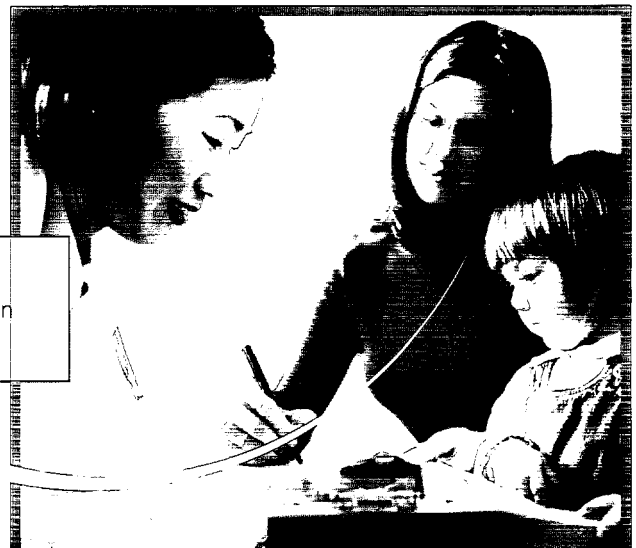
Cytyc's flagship product, the ThinPrep Pap Test, is the only replacement to the conventional Pap test that has FDA labeling claims stating that the product is significantly more effective than the conventional Pap smear for the detection of low-grade squamous intraepithelial (LSIL) and more severe lesions in a variety of patient populations. Additionally, data from a multi-site clinical outcome trial, in which 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.

We have grown our business through a direct sales force actively targeting OB/GYNs, insurance companies, and clinical laboratories. Through these relationships, Cytyc has emerged as the leader in cervical cancer screening with the ThinPrep Pap Test and now offers the FirstCyte Breast Test for breast cancer risk assessment. With the successful commercialization of the ThinPrep Pap Test, Cytyc has the experience required to educate physicians and gain reimbursement. We are poised to leverage these relationships to make the FirstCyte Breast Test available to women at risk for developing breast cancer.

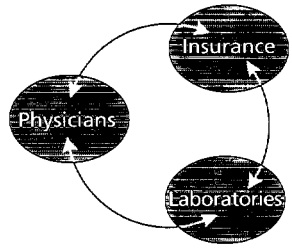
## 2 FirstCyte Breast Test: Establishing the Standard for Risk Assessment

In the U.S. there are 225,000 new cases of breast cancer diagnosed each year, and approximately five million women are at risk for developing breast cancer. To this end, Cytyc introduced the FirstCyte Breast Test, a proprietary ductal lavage technology, offering high-risk women and their physicians more medical information to develop a proactive risk management strategy. We believe this innovative technology, along with the well-established ThinPrep System, will continue to have a positive impact on women's healthcare and will further our mission to predict and prevent disease. Cytyc continues to gain traction within the medical and reimbursement communities for the FirstCyte Breast Test. Employing a multifaceted commercialization plan aimed at establishing the FirstCyte Breast Test as the standard for breast cancer risk assessment, Cytyc's leading OB/GYN sales team is actively targeting primary care gynecologists and trained breast centers in U.S. locations where reimbursement is most favorable.

A multi-site clinical outcome trial has shown a **59.7% increase** in the detection of high-grade lesions.



## 1 ThinPrep Pap Test




**Building Key Relationships**
An established sales and reimbursement structure for the ThinPrep Pap Test can be leveraged for the FirstCyte Breast Test.

## 2 FirstCyte Breast Test

| Predict and Prevent | Diagnose and Treat |
|---|---|

**Expanding the Medical Approach**
Detection of diseased tissues BEFORE they become invasive

Internationally, Cytyc operates in the United Kingdom, Switzerland, Germany, Sweden, France, Italy, Spain, Portugal, and Asia/Pacific-Australia.

## 3 Geographic Market Expansion: Reaching Women Worldwide

With more than 60 million Pap tests performed outside of the U.S. annually, the international markets represent a sizeable growth opportunity for Cytyc. By applying our successful formula to the international arena, we have implemented a focused strategy in key international markets to expand worldwide adoption of the ThinPrep Pap Test in order to increase international sales, which currently account for six to eight percent of total revenues.

During 2002, Cytyc focused sales and marketing efforts in Europe, where approximately 36 million Pap tests are performed each year. In October, Cytyc Iberia began operations serving Spain and Portugal. The creation of Cytyc Iberia increases Cytyc's strong international presence, joining existing operations in the United Kingdom, Switzerland, Germany, Sweden, France, Italy, and Asia/Pacific-Australia. While the process of public screening program acceptance and reimbursement has a long lead time in most countries, Cytyc's investment in key countries has set the foundation for future international growth.

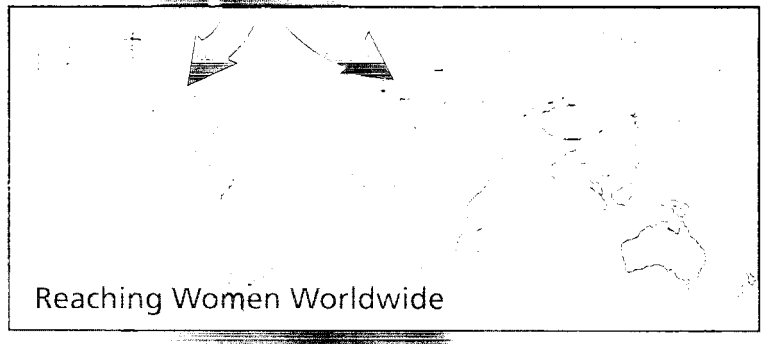
## 4 ThinPrep Imaging System: Improving Cervical Cytology Imaging

In the Company's early days, we counted among our goals the improvement of cervical cytology imaging. To achieve the goal of bringing computer imaging to cervical cytology screening, Cytyc developed the ThinPrep Imaging System, an automated imaging and review system for use with ThinPrep Pap Test slides.

The ThinPrep Imaging System is an interactive computer system that assists cytotechnologists and pathologists in the primary screening of ThinPrep Pap Test slides. The system combines imaging technology with an automated microscope to facilitate the identification of diagnostic fields of interest.

Cytyc received an Approvable Letter from the FDA for the ThinPrep Imaging System in December 2002 and expects to launch this new product during the second quarter of 2003. We believe this technology will further the positive impact on cervical cancer screening that we initiated in 1996 with the approval of the ThinPrep Pap Test.

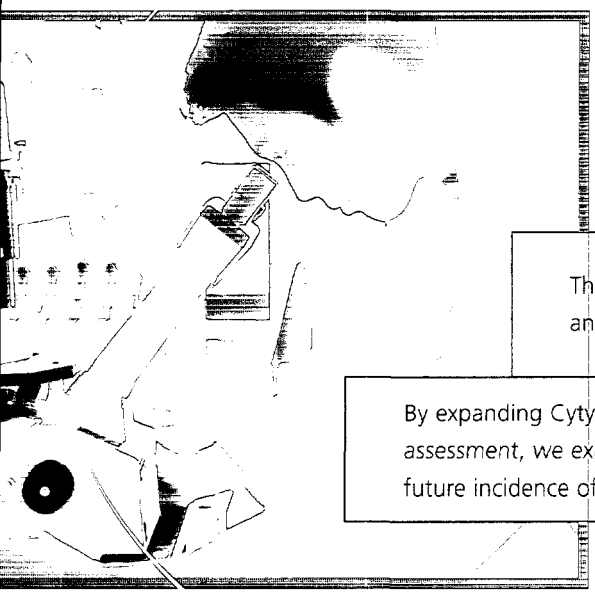
## 3 Geographic Market Expansion

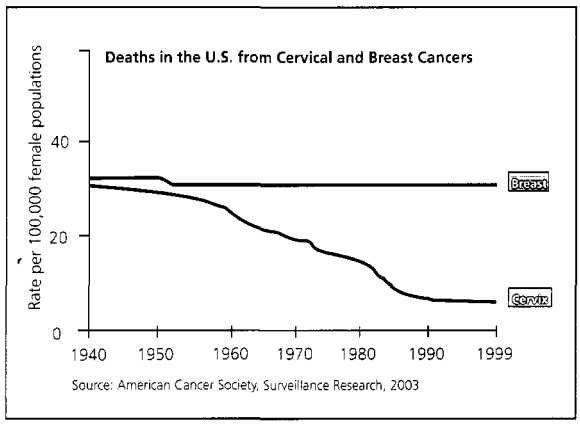



## 4 ThinPrep Imaging System

Continuously improving cervical cytology imaging

Computer-assisted Cervical Cytology





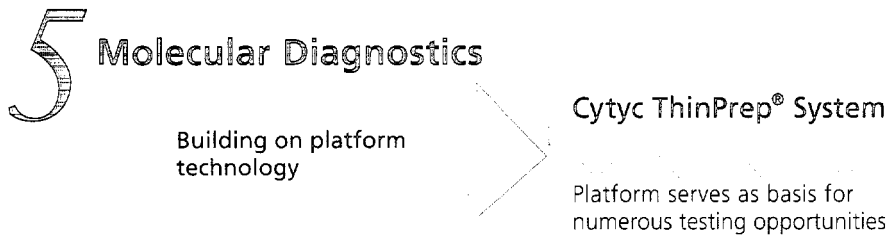

The Pap test has helped drastically **reduce** the incidence and mortality of **cervical cancer** in the past 60 years.

By expanding Cytyc's technology into breast cancer risk assessment, we expect to have a significant **impact** on the future incidence of **breast cancer**.

## 5 Molecular Diagnostics: Building On Platform Technology

The ThinPrep System serves as a platform for numerous testing opportunities and gives healthcare providers the ability to perform multiple diagnostic tests from a single patient sample. Tests include cervical cancer screening, and testing for human papillomavirus (HPV) using Digene Corporation's Hybrid Capture® 2 HPV Test, as well as *Chlamydia trachomatis* and *Neisseria gonorrhea* using Roche Diagnostics Corporation's COBAS AMPLICOR™ Analyzer. In addition, the ThinPrep System provides the platform for breast cancer risk assessment with the FirstCyte Breast Test. The ThinPrep System also offers the capability for other general cytology applications such as fine needle aspirates, mucoid specimens, and body fluids, as well as out-of-the-vial testing for molecular diagnostics.

Molecular diagnostic tests for cancer represent exciting growth opportunities for Cytyc over the next five years. The most attractive avenues to pursue include breast, ovarian, colon, bladder, prostate, and lung cancer markets. The broad applicability of Cytyc's ThinPrep technology platform has enabled us to capitalize on these additional testing opportunities. The out-of-the-vial capability and unparalleled proven clinical performance are key reasons many physicians have chosen the ThinPrep Pap Test.



# 2022 Financial Statements

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

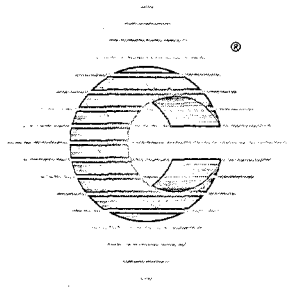
# FORM 10-K

☒ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the Fiscal Year Ended: December 31, 2002

or

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the transition period from _____ to _____

Commission File Number: 0-27558



C Y T Y C

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

| Delaware | 02-0407755 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 85 Swanson Road, Boxborough, Massachusetts | 01719 |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (978) 263-8000
Registrant's website: http://www.cytyc.com

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, and Series A Junior Preferred Stock Purchase Rights
(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. ☒

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

The aggregate market value of the voting stock held by nonaffiliates of the registrant as of June 28, 2002 (based on the closing price of $7.62 per share as quoted by The Nasdaq Stock Market as of such date) was $750,495,743. As of March 17, 2003, 113,002,299 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, 2002. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

Cytyc Corporation
Annual Report on Form 10-K
For the fiscal year ended December 31, 2002

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## Forward-Looking Statements

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. Our 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, research and development plans, regulatory uncertainties, potential savings to the healthcare system, management's assessment of market factors, as well as statements regarding our strategy and plans, constitute forward-looking statements that involve risks and uncertainties. In some cases these forward-looking statements can be identified by the use of words such as "may," "will," "should," "expect," "project," "predict," "potential" or the negative of these words or comparable words. The factors listed under "Certain Factors Which May Affect Future Results" in Part I, Item 1 – "Business", 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 our business, financial condition, and results of operations. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Accordingly, you are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made.

## PART I

### Item 1. Business

Throughout this Annual Report on Form 10-K, the words "we," "us," "our" and "Cytyc" refer to Cytyc Corporation and all of its affiliates and subsidiaries taken as a whole, and "our board of directors" refers to the board of directors of Cytyc Corporation.

### Overview of Business

Cytyc designs, develops, manufactures and markets a sample preparation system for medical diagnostic applications. Our 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 general, non-gynecological testing applications.

The ThinPrep System for cervical cancer screening is a replacement for the conventional Pap smear method and was approved by the United States Food and Drug Administration ("FDA") in 1996 as being significantly more effective in detecting low grade and more severe lesions than the conventional Pap smear method in a variety of patient populations. Our clinical trial data also indicates a 59.7% increase in the detection of high grade lesions with the ThinPrep System. Another advantage of the ThinPrep System is significantly improved specimen quality over that of the conventional Pap smear method. The ThinPrep System has been approved for use with both broom or combined endocervical brush and spatula sampling devices, the most commonly used methods of collecting samples for conventional Pap smears. We believe that the ThinPrep System improves accuracy in the detection of cervical cancer and precancerous lesions by making the slide, on which the patient's cell sample is deposited, more representative of the patient's clinical condition, improving preservation of the sample, standardizing the presentation of cells on the slide in a thin layer of cervical cells, and reducing the presence of mucus, blood and other obscuring debris.

The ThinPrep System consists of the ThinPrep® Processor and related disposable reagents, filters and other supplies (together, the disposable supplies used in gynecological applications of the ThinPrep System are referred to as the ThinPrep® Pap Test). The ThinPrep Processor is a table top device used to prepare cell specimens for analysis by a cytotechnologist or cell technician. Currently, we have over 1,800 ThinPrep Processors installed throughout the United States. The ThinPrep System also serves as a platform for additional gynecological applications, including testing for the human papillomavirus ("HPV") using Digene Corporation's ("Digene") Hybrid Capture® II HPV DNA Assay, from a single vial of patient specimen collected in ThinPrep solution. We have obtained FDA approval for PreservCyt®, a component of the ThinPrep System, to be used as a transport medium in testing for the sexually transmitted diseases Chlamydia trachomatis and Neisseria gonorrhea directly from the ThinPrep Pap Test vial using Roche Diagnostics Corporation's ("RDC") COBAS Amplicor™ automated system.

In November 2001, we acquired Pro•Duct Health, Inc. ("Pro Duct"), which developed proprietary ductal lavage technology to aid in breast cancer risk assessment. Using this technology, we introduced the FirstCyte™ Breast Test, which is currently used for women who are at high risk for breast cancer to detect atypical changes in cells lining the milk ducts, where an estimated 95 percent of all breast cancers originate. Our existing ThinPrep System can serve as a laboratory platform for preparing the cell sample from the FirstCyte Breast Test, which is a form of general cytology screening.

On February 19, 2002, we entered into an agreement and plan of merger with Digene Corporation, a Delaware corporation. In June 2002, we announced that the Federal Trade Commission had voted to seek to block our proposed acquisition of Digene. The five-member commission authorized the staff to seek a court order to prevent the acquisition from being consummated. On June 30, 2002, the merger agreement was terminated.

*Available Information.* Cytyc files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy any document we file at the SEC's public reference room at Room 1024, 450 Fifth Street, NW, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for information on the public reference room. The SEC maintains a website that contains annual, quarterly and current reports, proxy statements and other information that issuers (including Cytyc) file electronically with the SEC. The SEC's website is *http://www.sec.gov*.

Cytyc's website is located at *http://www.cytyc.com*. Cytyc makes available free of charge through its internet site its annual reports on Form 10-K; quarterly reports on Form 10-Q; current reports on Form 8-K; and any amendments to those reports filed or furnished pursuant to the Securities Exchange Act of 1934 (the "Exchange Act") as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information on Cytyc's website is not incorporated by reference into this report.

*Incorporation.* Cytyc was incorporated in Delaware in 1987.

## Cervical Cancer and the Conventional Pap Smear

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, physicians in the United States and throughout the world typically recommend regular 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.

Cervical cancer screening has been conducted since the late 1940s using the conventional 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 during the past 60 years has contributed to a greater than 70% decrease in mortality from cervical cancer. The Pap smear is currently the most widely used screening test for the early detection of cervical cancer in the United States. It is estimated that over 110 million Pap smears are performed worldwide on an annual basis, with approximately 50 million of those being performed in the United States.

## The Conventional 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 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 into either of two categories: (i) satisfactory for evaluation or (ii) unsatisfactory for evaluation.

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 2001 Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses ("2001 Bethesda System") into one of the following categories: (i) Negative for intraepithelial lesion or malignancy; (ii) Atypical Squamous Cells of Undetermined Significance ("ASC-US") or Atypical Squamous Cells—Cannot Exclude High-Grade ("ASC-H"); (iii) Atypical Glandular Cells ("AGC"); (iv) Endocervical Adenocarcinoma In Situ ("AIS"); (v) Low-Grade Squamous Intraepithelial Lesions ("LSIL"); (vi) High-Grade Squamous Intraepithelial Lesions ("HSIL"); and (vii) Adenocarcinoma. Any slide classified as other than "negative for intraepithelial lesion and malignancy" 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 2001 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 conventional Pap smear 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 a successful outcome. Reports of the false negative rate of the conventional Pap smear 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 published in February 1999 by the Agency for Health Care Policy and Research, a division of the U.S. Department of Health and Human Services. The "Evaluation of Cervical Cytology" evidence report published by that agency concluded that the false negative rate for the conventional Pap smear is approximately 49% and that approximately 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 the conventional Pap smear method 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 abnormal cells that would be 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 of the slide difficult. 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. We believe 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 either two sample collections during the patient's initial visit to the physician, or 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. We believe 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 ThinPrep System, which was cleared for marketing as a replacement for the conventional Pap smear method for cervical cancer screening by the FDA in 1996, is designed to reduce the incidence of false negative

diagnoses, improve slide quality, reduce inconclusive slide evaluations and enable a single sample to be used for additional diagnostic testing. The ThinPrep System for gynecological applications consists of the ThinPrep Processor and the ThinPrep Pap Test (disposable reagents, filters and other supplies). We currently offer two types of processors to laboratory customers: the ThinPrep 2000 Processor, our primary processor, which processes one sample at a time; and the ThinPrep 3000 Processor, our batch processor, which can be loaded with up to 80 samples for automatic processing. Currently, we have over 1,800 ThinPrep Processors installed throughout the United States.

### The ThinPrep Process

We believe 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, improved productivity in screening by reducing cytotechnologist fatigue and the time required to examine each slide and the ability to permit multiple tests to be conducted from a single sample.

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 our 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 our 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 cell collection process in order to prevent the cellular concentration from being too scant or too dense. A thin layer of cells is then transferred from the filter to a glass slide in a 20 mm-diameter circle and the slide is automatically deposited into a fixative solution.

Our proprietary reagents and supplies include PreservCyt Solution to collect and transport cervical samples to the laboratory for optimal cell preservation and TransCyt Filters to reduce non-diagnostic debris and mucus and collect cells. We also sell ThinPrep® Microscope Slides, high-quality microscope slides manufactured to our specifications, which improve cell adhesion to the slide.

### A Significant Improvement Over the Conventional Pap Smear

The FDA has approved the ThinPrep System as "significantly more effective" in detecting low grade and more severe lesions than the conventional Pap smear method in a variety of patient populations. Our multi-site clinical trial data also indicate a 59.7% increase in the detection of high grade lesions with the ThinPrep System. One of the reasons that the ThinPrep system is more effective is the significant improvement in specimen quality, as embodied in FDA claims, using the ThinPrep System over that of the conventional Pap smear method. We believe 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.

The ThinPrep System has been approved by the FDA for use with either a "broom-type" device or a combination of endocervical brush and spatula sampling devices, commonly used methods of collecting samples for conventional Pap smears, making the transition to the ThinPrep System a simple one for physicians.

*Additional Gynecological Applications*

The ThinPrep System has been approved by the FDA to serve as a platform for additional gynecological applications, including testing for HPV using Digene's Hybrid Capture II HPV DNA Assay from a single vial of patient specimen collected in PreservCyt Solution and in testing for Chlamydia trachomatis and Neisseria gonorrhea directly from the ThinPrep Pap Test vial using RDC's COBAS Amplicor automated system.

*Clinical Studies*

Since FDA approval, a number of studies have been published or presented that evaluate the ThinPrep Pap Test. To date, more than 40 major studies evaluating the performance of the ThinPrep Pap Test compared to the conventional Pap smear have been published in peer-review 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. The studies consistently demonstrate significant increases in the detection of precancerous cervical lesions. Of particular importance is the number of studies demonstrating statistically significant increases in the detection of high-grade cervical lesions, which are the immediate precursors to cervical cancer. In total, more than 100 studies have been published, in more than 20 separate journals, demonstrating a wide range of benefits including increased disease detection, reduction of equivocal diagnoses and false negatives, improved specimen adequacy, adjunctive molecular testing, morphology assessment, and cost effectiveness.

In April 2002, new patient management consensus guidelines were published in the Journal of the American Medical Association ("JAMA"). The guidelines, developed by a panel of 121 medical experts including representatives from 29 leading medical organizations, state that automatic or "reflex" testing for human papillomavirus DNA is the "preferred approach" for patients with borderline Pap results. Such "reflex" HPV DNA testing can be performed directly from a liquid-based Pap test sample collected at the initial office visit, thus eliminating the need for a return visit. The ThinPrep Pap Test is the only liquid-based Pap test currently approved by the FDA for HPV DNA testing directly from the vial using Digene's Hybrid Capture II HPV DNA Assay, the only FDA-approved test for HPV.

General, Non-Gynecological Cytology

In addition to acting as a replacement for the conventional Pap smear, the ThinPrep System also offers significant improvements for general, non-gynecological cytology screening applications. General cytology applications include fine-needle aspiration specimens (e.g. breast, thyroid, lung or liver), lavage specimens (e.g. breast, gastrointestinal), body fluids (e.g. urine, pleural fluid, ascitic fluid, pericardial fluid), respiratory specimens (e.g. sputum, brushing of respiratory or gastrointestinal tracts) and ancillary testing (e.g. cell blocks, immunocytochemistry, special stains). The ThinPrep System provides significant improvements over other methods of general cytology screening by optimizing cell preservation through use of our CytoLyt and PreservCyt Solutions, standardizing preparation of specimens using the gentle dispersion and transfer process of the ThinPrep 2000 Processor, simplifying slide screening by offering one single, well-preserved slide per case and allowing laboratories to perform additional ancillary testing out of one PreservCyt Solution vial.

FirstCyte Breast Test

In November 2001, we acquired Pro Duct, which developed proprietary technology for performing ductal lavage, a test that obtains cells from the breast ducts for laboratory assessment. Using this technology, we introduced the FirstCyte Breast Test, which is currently used as a risk assessment tool for women who are at high risk for breast cancer. The test detects atypical changes in cells lining the milk ducts, where an estimated 95 percent of all breast cancers originate. Breast cancer is a progressive disease. By identifying high risk women who are harboring atypical ductal epithelial cells and who are apparently at highest risk for developing breast cancer, the FirstCyte Breast Test assists in decision making about appropriate preventative measures and enables doctors to move to a paradigm of predicting and preventing breast cancer, rather than the current paradigm of detection and treatment. The FirstCyte Breast Test can be administered by trained obstetrician/gynecologists,

radiologists or breast surgeons and is to be used in conjunction with mammography, clinical exams, breast self-exams and other standard breast cancer detection methods. Our existing ThinPrep System can serve as a laboratory platform for preparing the cell sample from the FirstCyte Breast Test, which is a form of general cytology screening.

## Research and Development

Our core research and development strategy is to continue to develop innovative medical diagnostic applications of the ThinPrep System. Consistent with this strategy, we are currently evaluating additional diagnostic applications of our ThinPrep technology in testing for the presence of other types of cancers and sexually transmitted diseases. In addition, we continue to enhance the FirstCyte Breast Test technology while driving adoption.

*ThinPrep Imaging System*

We are currently awaiting final FDA approval for our ThinPrep Imaging System, following receipt of an "Approvable" letter from the FDA in December 2002. The ThinPrep Imaging System is an interactive computer system that 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 an automated microscope to facilitate locating these fields. The system is expected to increase a cytology laboratory's screening productivity and diagnostic accuracy while leveraging the increased sensitivity of the ThinPrep Pap Test. The effect on productivity may be affected by regulatory limitations imposed on the number of tests that may be performed per day as is the case with the ThinPrep System and conventional Pap smears. No assurance can be given regarding limits that may be applicable to the ThinPrep Imaging System. Our application to the FDA 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 Approvable letter stated that the ThinPrep Imaging System is approvable subject to the FDA's inspection of our manufacturing facility. This letter usually represents the final step before a product receives FDA clearance for marketing in the United States. We expect FDA approval of the ThinPrep Imaging System to occur in the first half of 2003.

There can be no assurance that we will be successful in developing or marketing additional applications of the ThinPrep System. Furthermore, any additional applications may require additional approvals from the FDA 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.

Our expenditures for research and development (which includes clinical trials, regulatory affairs and engineering) were approximately $14.2 million, $19.0 million, and $14.5 million for the years ended December 31, 2000, 2001 and 2002, respectively. Research and development for 2001 excludes a one-time charge of $56.0 million for in-process research and development related to the Pro Duct acquisition.

## Business Development

We are continually evaluating a variety of new business opportunities that would leverage our existing technology and distribution channel. We believe molecular-based diagnostic tests for cancer, particularly those for breast, ovarian, colon, bladder, prostate, and lung cancers, represent growth opportunities. Business opportunities in this area include direct funding of research projects, equity investments for marketing rights to new diagnostic products or acquisitions to provide new technologies and/or product offerings.

## Marketing and Sales

*Domestic*

Our marketing and sales strategy is to achieve broad market acceptance of the ThinPrep System for cervical cancer screening and other diagnostic applications, including the FirstCyte Breast Test. A critical element of our strategy in the United States is to utilize the results of our clinical trials and expanded FDA labeling to

demonstrate the safety and efficacy of the ThinPrep System to healthcare providers, clinical laboratories and third-party payors. As of December 31, 2002, we have an installed base of over 1,800 ThinPrep Processors at customer sites in the United States. In addition, we have trained over 1,100 laboratories in the use of the ThinPrep System and 39,750 of the 44,500 physicians that use the ThinPrep System utilize it on over 50% of the Pap tests they perform. This has allowed us to obtain a market share of approximately 61% of the Pap test market in the United States. The ThinPrep Pap Test is covered by primarily all health plans in the United States.

We expect to continue to expand our market reach through marketing by our direct sales force of over 200 customer and technical service representatives, with approximately 80% focused on healthcare providers, 15% focused on clinical laboratories, and 5% focused on third-party payors. Our sales force has been trained to sell all of our product offerings, including the FirstCyte Breast Test. We expect to leverage our strong brand name and existing relationships with healthcare providers and third-party payors to successfully market the FirstCyte Breast Test. To date, we have trained 166 laboratories and 263 clinicians in the performance of the FirstCyte Breast Test and have obtained insurance coverage for the FirstCyte Breast Test through 22 payors representing 29 million covered lives.

In addition to our direct sales force, we have entered into certain marketing relationships with third parties. In January 2000, we entered into a supply and co-marketing agreement with Quest Diagnostics Incorporated ("Quest") to market our ThinPrep Pap Test as Quest's exclusive liquid-based cervical cancer screening methodology. In January 2001, we also entered into an agreement with Digene, exclusive in the United States and Puerto Rico, to co-promote the benefits of testing for HPV using Digene's Hybrid Capture II HPV DNA Assay directly from the ThinPrep collection vial. These agreements have been useful in augmenting our direct sales efforts to achieve broad market acceptance of the ThinPrep System. However, due to the strong market position of the ThinPrep Pap Test, the differentiation of the ThinPrep Pap Test in the marketplace as a result of our clinical trials and expanded FDA labeling, the strength of our direct sales efforts, and potential alternative testing platforms, we have reduced our focus on these third-party marketing relationships. On December 31, 2002, the co-marketing and sales agreement with Quest expired and we continue to sell to them under a nonexclusive supply arrangement. Our co-promotion agreement with Digene expires in June 2003 and it is uncertain as to whether a new agreement will be executed. In addition, in September 2002, we terminated our exclusive agreement with RDC to co-promote the benefits of using RDC's COBAS Amplicor automated system to test for Chlamydia trachomatis and Neisseria gonorrhea directly from the ThinPrep Pap Test vial. The decision to terminate this arrangement was based in part on requests from lab customers for alternative options and testing platforms. In addition to potential renewal of these particular third-party marketing relationships, we are actively pursuing additional partners to make the ThinPrep platform available for other diagnostic tests and increase market acceptance of the FirstCyte Breast Test.

*Worldwide*

Our worldwide strategy is to establish selling channels 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. To accomplish this, we have established subsidiaries in six European countries, including our recently established subsidiary in Spain. In addition, we have a subsidiary in Australia, as well as branches in Hong Kong and Japan. These entities have been established to handle sales, service, training and distribution to clinical laboratories in European and Asian markets.

We believe that international sales efforts will continue to involve a lengthy process, requiring us 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. In order to effectively market the ThinPrep System for cervical cancer screening and any other new products and applications on a worldwide basis, we will need to continue to increase our international marketing and sales capabilities.

**Third-Party Reimbursement**

The cost of the ThinPrep Pap Test, plus a laboratory mark-up, is generally billed by laboratories to third-party payors and results in a higher reimbursement amount for the ThinPrep Pap Test than the current reimbursement paid for conventional Pap smears. 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, Medicare and Medicaid and foreign governmental agencies. 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 or other methods. In addition, we will be required to secure adequate third-party reimbursement for any new products we develop or obtain, including the FirstCyte Breast Test.

Since January 1, 1998, our laboratory customers have been able to request reimbursement for the ThinPrep Pap Test from health insurance companies and the Centers for Medicare and Medicaid Services ("CMS") using a Current Procedural Terminology ("CPT") code specifically for liquid-based thin layer 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 limitation amount for reimbursement of $28 for the CPT codes describing the ThinPrep Pap Test. This is nearly double the national limitation amount for reimbursement of the conventional Pap smear.

Our direct sales force is actively working with current laboratory customers and health insurance companies to facilitate reimbursement of the ThinPrep Pap Test under the CPT code. As of December 31, 2002, based on information provided to us, we believe that all of the health insurance companies which announced coverage of the ThinPrep Pap Test, representing over 90% of insured women in the United States, have implemented the CPT code and have established a reimbursement amount.

Effective January 1, 2003, a Category III CPT code for emerging technology has been assigned for the FirstCyte Breast Test. CMS has not established a national limitation amount for the FirstCyte Breast Test. The FirstCyte Breast Test is currently being reimbursed by private health insurance companies at between $500 to $600 per duct, with a current average of 1.5 ducts lavaged per patient undergoing a FirstCyte Breast Test.

Lack of or inadequate reimbursement by government and other third-party payors for our products would have a material adverse effect on our 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 our products under any other reimbursement system.

**Raw Materials and Manufacturing**

We purchase many of the components and raw materials used in our ThinPrep System and the FirstCyte Breast Test from numerous suppliers in the U.S. and abroad. In some cases, we have established long-term supply contracts with our suppliers. For reasons of quality assurance, sole source availability or cost effectiveness, certain components and raw materials are available only from a sole supplier. We work closely with our suppliers to assure continuity of supply while maintaining high quality and reliability. Due to the FDA's requirements regarding manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials. Generally, we have been able to obtain adequate supplies of such raw materials and components. In the event that we are unable to obtain sufficient quantities of raw materials or components on commercially reasonable terms or in a timely manner, we would not be able to manufacture our products on a timely and cost-competitive basis, which would have a material adverse effect on our business, financial condition and results of operations.

We assemble all ThinPrep Processors and manufacture filters at our facility in Boxborough, Massachusetts. We fill all of our vials at our facility in Londonderry, New Hampshire.

### Quality Management

We place significant emphasis on providing quality products and services to our customers. A major portion of our quality systems relate to the design and development, manufacturing, packaging, sterilization, handling, distribution and labeling of our products. These quality systems, including control procedures that are developed and implemented by technically trained professionals, result in rigid specifications for product design, raw materials, components, packaging materials, labels, sterilization procedures and overall manufacturing process control. Our quality systems integrate the efforts of suppliers of raw materials, components and finished goods to ensure we meet customer and regulatory requirements. These systems are designed to ensure that all appropriate standards and requirements are met before goods are released.

Certain of our operation facilities are certified under ISO 9001, an international quality standard. In October 2002, we successfully completed inspection by the National Standards Authority of Ireland (NSAI), which certified our quality control system for compliance with ISO 13485, ensuring compliance with Canadian Medical Device Regulations and replacement of EN 46001 in Europe. There can be no assurance that we will be able to maintain compliance with ISO requirements or that failure to maintain compliance with these requirements will not have a material adverse effect upon our business, financial condition and results of operations.

### 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. Our existing products are regulated in the United States as medical devices by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDC Act"). The ThinPrep System required premarket application ("PMA") approval prior to commercial distribution, which demonstrated to the FDA that the ThinPrep System is safe and effective for its intended use. The devices which comprise the FirstCyte Breast Test required the filing of 510(k) submissions prior to commercial distribution, which demonstrated that the devices are substantially equivalent to legally marketed devices that are not subject to PMA 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 approve 510(k) clearance or PMA approval for a device, withdrawal of clearances or approvals, total or partial suspension of production, fines, injunctions, civil penalties, recall or seizure of products, and criminal prosecution.

The FDA's regulations may require agency approval of a PMA supplement or a new 510(k) notification 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 regulatory approval process can be expensive, lengthy and uncertain. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals for any proposed future products or modifications of existing products. The failure to obtain clearances or approvals, loss of previously received approvals, or failure to comply with existing or future regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations.

The ThinPrep System for cervical cancer screening received PMA approval in 1996. In 2000, the FDA approved the ThinPrep 3000 Processor, our batch processor for automated sample preparation. In June 2002, the FDA approved our PMA supplement application to allow for testing for Chlamydia trachomatis and Neisseria gonorrhea directly from the ThinPrep Pap Test vial using RDC's COBAS Amplicor automated system. In

January 2002, we submitted a PMA application to the FDA for the ThinPrep Imaging System. In December 2002 we received an "Approvable" letter from the FDA related to this application, which stated that the PMA application for the ThinPrep Imaging System is approvable subject to the FDA's inspection of our manufacturing facility. This letter usually represents the final step before a product receives FDA approval for marketing in the United States. There can be no assurance that such approval will be obtained on a timely basis, or at all. We anticipate that any other proposed uses for the ThinPrep System may require approval of a PMA supplement or a new PMA application.

The ThinPrep System is, and any other products we may manufacture or distribute 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, compliance with the FDA's Quality System Regulation requirements and other actions as deemed necessary by the FDA. We are 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 us and any of our 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 our ability to market or sell the ThinPrep System, the FirstCyte Breast Test, or any other products we may develop or obtain.

We are also subject to various federal and state laws pertaining to health care fraud and abuse, including federal and state anti-kickback laws. Anti-kickback laws make it illegal for an entity to solicit, offer, receive, or pay remuneration in exchange for, or to induce, the referral of business or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any item or service paid for by Medicare, Medicaid or certain other federal health care programs. The statute has been broadly interpreted to cover a wide array of practices. Some states have passed similar laws. The federal government has published regulations that identify "safe harbors," which if applicable will assure that certain arrangements will not be found to violate the federal anti-kickback statutes. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. We seek to comply with the safe harbors where possible. Due to the breadth of the statutory provisions and the absence of extensive guidance, it is possible that our practices might be challenged under federal anti-kickback or similar laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to raise questions about our behavior or find that we have violated these laws, there could be a material adverse effect on our business, including our stock price. Our activities could be subject to challenge for the reasons discussed above, due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

We also are 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 we 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 our 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 we 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. Our failure 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 our 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. We believe 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**

We rely on a combination of patents, trademarks, trade secrets, copyrights and confidentiality agreements to protect our proprietary technology, rights and know-how. We pursue patent protection in the United States and file corresponding patent applications in certain foreign jurisdictions. We hold 24 issued United States patents, 39 pending United States patent applications, and corresponding foreign patents or patent applications relating to various aspects of our ThinPrep, FirstCyte and other related technologies. There can be no assurance, however, that pending patent applications will ultimately issue as patents or that the claims allowed in any of our existing or future patents will provide competitive advantages for our products or will not be successfully challenged or circumvented by competitors. We cannot be sure that our products or technologies do not infringe patents that may be granted in the future pursuant to pending patent applications or that our products do not infringe any existing patents or proprietary rights of third parties. In the event that any relevant claims of third-party patents are upheld as valid and enforceable, we could be prevented from selling our products or could be required to obtain licenses from the owners of such patents or be required to redesign our products to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be on terms acceptable to us or that we would be successful in any attempts to redesign our products or processes to avoid infringement. Our failure to obtain these licenses or to successfully redesign our products would have a material adverse effect on our business, financial condition and results of operations.

There can be no assurance that the obligations of our employees and third parties with whom we have entered into confidentiality agreements to maintain the confidentiality of our trade secrets and proprietary information, will effectively prevent disclosure of our confidential information or provide meaningful protection for our confidential information if there is unauthorized use or disclosure, or that technology similar to ours will not be independently developed by our competitors. In addition, we are the exclusive perpetual worldwide licensee of certain patented technology from DEKA Products, LP ("DEKA") for use in the field of cytology related to the fluid pumping system used in the ThinPrep System. We are obligated to pay royalties equal to 1% of net sales of the ThinPrep Processor and filter cylinder disposable products which are used in the ThinPrep System. 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 us in the event that the license is assigned to other than a single acquirer of Cytyc without the consent of DEKA. In addition, we are the exclusive licensee of certain patented technology from the Regents of the University of California for use in the field of diagnosis and treatment of breast cancer. We are obligated to pay royalties equal to 3% of net sales of the FirstCyte Breast Test catheters. Our failure to maintain rights to such technology could have a material adverse effect on our business, financial condition and results of operations. We also hold unregistered copyrights on internally-developed documentation and operating software developed for the ThinPrep System. We presently have 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 we own will provide competitive advantages for our products or will not be challenged or circumvented by our competitors.

Litigation may be necessary to defend against claims of infringement, or to enforce our patents, copyrights, trademarks or trade secrets which could result in substantial cost to us and diversion of focus away from our business. In addition, the laws of some foreign countries do not protect our 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 our business, financial condition and results of operations. We face direct competition from a number of publicly-traded and privately-held companies, including other manufacturers of thin layer slide preparation systems. Several established medical device manufacturers produce thin layer slide preparation systems for use in general, non-gynecological testing applications, at least one of which has achieved brand-name recognition and significant penetration in the general, non-gynecological cytology market. In addition to direct competition, we face 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. We believe 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, our ability to market our products to such hospitals and laboratories could be materially adversely affected.

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

We compete on the basis of a number of factors, including product quality and performance, manufacturing efficiency, marketing and sales capabilities and customer service and support. There can be no assurance that we will be able to compete successfully against current or future competitors or that competition, including the development and commercialization of new products and technologies, will not have a material adverse effect on our business, financial condition or results of operations.

### Customers

Quest Diagnostics, Inc. and Laboratory Corporation of America accounted for 20% and 13% of our consolidated net sales, respectively, for the year ended December 31, 2002. Quest represented 19% and 20% of our consolidated net sales for the years ended December 31, 2000 and 2001, respectively. During 2000 and 2001, no other customers represented 10% or more of consolidated net sales. On December 31, 2002, our exclusive sales agreement with Quest expired and we continue to sell to them under a nonexclusive supply arrangement.

### Employees

As of December 31, 2002, we employed 626 persons worldwide. We are not subject to any collective bargaining agreements, have never experienced a work stoppage and consider our relations with our employees to be good.

### Financial Information Regarding Segment Reporting and Geographic Areas

We currently operate in one segment, medical diagnostic equipment. Please refer to Note 2(t) *"Segment and Enterprise-Wide Reporting"* in the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K under Item 8, "Financial Statements and Supplementary Data."

### Certain Factors Which May Affect Future Results

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 our business, financial condition, and results of operations.

The following discussion of our 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, filters, and other supplies for use in gynecological and general, 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 ThinPrep 3000 Processor and FirstCyte Breast Test and we have received an "Approvable" letter from the FDA related to our ThinPrep Imaging System, we have not yet generated significant revenues from these products. We cannot guarantee 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 FirstCyte Breast Test, or that we will otherwise be able to generate significant revenue from sales of this product. 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 distribution of medical diagnostic devices generally require FDA clearance or 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 ongoing compliance with regulatory requirements. In January 2002, we submitted a PMA application to the FDA for the ThinPrep Imaging System to aid in cervical cancer screening. In December 2002, we received an "Approvable" letter from the FDA for this product. An Approvable letter usually represents the final step before a product receives PMA approval for marketing in the United States. In the letter, the FDA stated that the PMA application for the ThinPrep Imaging System is approvable subject to the FDA's inspection of our manufacturing facility. We do not know whether the FDA will approve this product 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, including the FirstCyte Breast Test and ThinPrep Imaging System. The laboratory cost of using the ThinPrep System and ThinPrep Imaging System for cervical cancer screening is higher than that of a conventional Pap smear and competing thin-layer slide preparation systems. The ThinPrep Imaging System is expected to increase a cytology laboratory's screening productivity and diagnostic accuracy, but the ability to increase productivity may be affected by regulatory limitations imposed on the number of tests that may be performed per day using the ThinPrep Imaging System, as is the case with the ThinPrep System and conventional Pap smears. No assurance can be given regarding limits that may be applied to the ThinPrep Imaging System and a low limit may adversely affect market acceptance of the ThinPrep Imaging System. 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 (i) a reduction in costs often associated with conventional Pap smears or competing thin-layer slide preparation systems, such as inaccurate diagnoses and the need for repeat Pap smears, as well as (ii) the ability to use our ThinPrep System for additional testing applications, such as testing for the human papillomavirus ("HPV"), Chlamydia trachomatis and Neisseria gonorrhea. In particular, for both the ThinPrep System and the FirstCyte Breast Test, we need to convince healthcare providers, insurance companies and other third party payors, and clinical laboratories of the clinical benefits and cost-effectiveness of these products.

*Some of our activities may subject us to risks under federal and state laws prohibiting "kickbacks" and false or fraudulent claims.*

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal health care program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, laboratories and other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Since we may provide some coding and billing advice to purchasers of our products, and since we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

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

We cannot sell our ThinPrep System and the FirstCyte Breast Test 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 majority 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 or the products of our competitors. We also will be required to secure adequate reimbursement for any new products we develop or obtain, including the FirstCyte Breast Test, and we may not be able to do so successfully.

*We are dependent upon a relatively small number of large clinical laboratory customers in the United States for a significant portion of our sales.*

We are dependent upon 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, or maintain our pricing levels with, 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.

*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. 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 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 personnel, operations and technologies of 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 any companies we may 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. 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.

*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.

*Product liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.*

The sale and use of our products could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to detect a disorder for which it was being used to screen. A product liability claim could result in substantial damages and be costly and time-consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

*Our quarterly operating results may vary.*

Our operating results have fluctuated significantly in the past on a quarterly basis. We expect that our operating results may fluctuate significantly from quarter to quarter and we may experience losses in the future depending on a number of factors, including the extent to which our products continue to 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 and level of reimbursement for our products by third-party payors, and other factors, many of which are outside our control.

*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. 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 favorable third-party reimbursements and required regulatory approvals in foreign countries. We may also face difficulty and added expense in complying with the U.S. and foreign regulations applicable to the sale and marketing of our products outside of the United States.

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

In addition to cervical cancer screening, the ThinPrep System serves as a platform for other gynecological applications, including testing for HPV using Digene's Hybrid Capture II HPV DNA Assay and testing for the sexually transmitted diseases Chlamydia trachomatis and Neisseria gonorrhea using RDC's COBAS Amplicor automated system. 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 may not be able to successfully promote, commercialize or develop additional uses of our technology.

*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 and in the field of breast cancer detection and treatment related to the FirstCyte Breast Test. 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 propriety filter material, from single sources. If we are unable to obtain sufficient quantities of these components that meet our quality and technical requirements at reasonable prices and in a timely manner, we will not be able to manufacture and sell our products on a timely and cost-competitive basis, which would materially and adversely affect our business and financial condition.

*Our lack of redundant manufacturing facilities could harm our business.*

We assemble all of our ThinPrep Processors and filters at our facility in Boxborough, Massachusetts. We fill all of our vials at our facility in Londonderry, New Hampshire. The loss of either of these facilities would likely

impede our manufacturing and sales efforts, which would materially and adversely affect our business and financial condition. We are currently working to establish site redundancy for our facility in Boxborough, Massachusetts. We are also working to establish an additional fill line in our Londonderry, New Hampshire but are not planning at this time to establish a redundant site for this facility.

## Executive Officers of Cytyc Corporation

The executive officers of Cytyc Corporation are set forth below. Business experience for the past five years is provided in accordance with SEC rules.

| | |
|---|---|
| *Patrick J. Sullivan (51).* | Chief Executive Officer and Director (since March 1994). Concurrently serves as President (since July 2002, previously from March 1994 to January 2002). Chairman of the Board (since May 2002). |
| *Robert L. Bowen (53).* | Vice President, Chief Financial Officer and Treasurer (since December 2000). Chief Financial Officer—Europe for Case Corporation (October 1997 to June 2000). |
| *Daniel J. Levangie (52).* | Executive Vice President of Cytyc Corporation and Chief Executive Officer and President of Cytyc Health Corporation (since July 2002). Mr. Levangie has held several positions with Cytyc Corporation, including President, Executive Vice President, Chief Operating Officer, Senior Vice President and Vice President, Commercial Operations (December 1997 to July 2002). |
| *Christopher A. Bleck (46).* | Vice President, Commercial Operations (since December 2001). Corporate Vice President/General Manager Pediatric Products for Ross Products/Abbott Labs (1999 to 2001). Mr. Bleck held several positions with Abbott Labs, including Vice President Managed Care, Vice President Business Development for Abbott International, and President/ General Manager Abbott Canada (1983 to 1999). |
| *Laura Deming (41).* | Vice President, Research and Development (since October, 2002). Senior Director of Product Development for Applied BioSystems (July 1996 to October 2002). |
| *Anita Graham (32).* | Vice President, Human Resources (since May 2002). Vice President, Human Resources for Serono, Inc. (September 2000 to January 2002). Sr. Vice President of Compensation Benefits and International Human Resources for Scudder Kemper Investments, now part of Deutsche Bank (February 1995 to July 2000). |
| *James M. Linder, M.D. (48).* | Chief Medical Officer (since January 2002). Consulting Medical Director (May 1996 to January 2002). |
| *A. Suzanne Meszner-Eltrich (50).* | General Counsel and Secretary (since September 1997). Concurrently served as Vice President, Human Resources (September 1997 to May 2002). |
| *Victoria S. Robinson (46).* | Vice President, Business Development (since August 2000). Vice President, Marketing (January 1998 to August 2000). |
| *Peter J. Rowden (47).* | Vice President, Operations (since December 2000). Director, Operations (January 1997 to December 2000). |
| *Leslie Teso-Lichtman (44).* | Vice President and Controller (since June 1998). Vice President of Finance, Treasurer and Secretary for Matritech, Inc. (March 1992 to May 1998). |

## Item 2. Properties

Our executive offices, research, and certain manufacturing and distribution 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. We also own approximately 2.7 acres of land and 46,000 square feet of facilities housing additional manufacturing operations in Londonderry, New Hampshire. In November 2001, as part of our acquisition of Pro Duct, we entered into a lease for a facility in Menlo Park, California consisting of approximately 35,000 square feet. The lease of this facility terminates on April 30, 2003. We have subleased all but 3,500 square feet of this office to third parties for the remainder of the lease term and have abandoned the facility. In November 2002, we entered into a lease for a distribution facility consisting of approximately 37,000 square feet in Methuen, Massachusetts, which we expect to be operational in mid-2003. We believe that we have or are in the process of acquiring adequate facilities to satisfy our operational requirements for the foreseeable future.

## Item 3. Legal Proceedings

On December 13, 2002, a purported federal securities class action lawsuit was filed in the United States District Court for the District of Massachusetts against us and two of our officers, on behalf of a purported class of all persons who purchased our common stock between July 25, 2001 and June 25, 2002. The complaint alleges that the defendants failed to disclose material facts and made materially misleading misstatements about our historical and future financial performance. Since the initial suit was filed, five additional suits were filed in the same court, making the same or substantially similar allegations. Motions to consolidate the six actions into a single proceeding have been filed with the court. We believe that the allegations are without merit and intend to defend ourselves vigorously. Given the early stage and current status of the litigation, we are unable to reasonably estimate the ultimate outcome of this case, and accordingly, minimal expense related to legal fees has been recorded to date.

In September 1999, we filed suit against TriPath Imaging, Inc. ("TriPath") for patent infringement in relation to our patent titled "Cell Preservative Solution". In January 2001, Cytyc and TriPath settled all litigation between the two companies. Each party dismissed all pending claims and counterclaims against each other with prejudice. We 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 our accompanying balance sheet due to certain restrictions on selling such shares for a period of two years ending January 2003, as well as a receivable from TriPath.

We are also involved in various other lawsuits and claims arising in the normal course of business. Although the outcomes of these other lawsuits and claims are uncertain, we do not believe any of them will have a material adverse effect on our business, financial condition or results of operations.

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

There were no matters submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2002.

## PART II

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

Our 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 our common stock on The Nasdaq Stock Market. These prices do not include retail mark-up, mark-down or commissions and may not represent actual transactions.

| | High | Low |
|---|---|---|
| 2001: | | |
| First Quarter | $22.67 | $13.63 |
| Second Quarter | 26.03 | 14.50 |
| Third Quarter | 27.01 | 18.67 |
| Fourth Quarter | 30.22 | 21.65 |
| 2002: | | |
| First Quarter | $27.99 | $19.24 |
| Second Quarter | 27.53 | 5.73 |
| Third Quarter | 11.69 | 6.78 |
| Fourth Quarter | 11.48 | 8.19 |

On March 17, 2003, the last reported sales price of our common stock on the Nasdaq National Market was $12.46 per share. As of March 17, 2003, there were approximately 520 holders of record of our common stock.

We have never declared nor paid cash dividends.

On January 1, 2000, we issued a warrant to Quest to purchase up to 900,000 shares of our 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 we issued Quest 494,400 shares of our common stock. We made such issuance 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, we completed the acquisition of Pro Duct. We 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 Cytyc Health Corporation, our wholly-owned subsidiary, resulting in Cytyc Health Corporation surviving the merger and continuing in existence as our wholly-owned subsidiary.

In connection with our acquisition of Pro Duct, we issued an aggregate of approximately 5,000,000 shares of our common stock valued at $137.7 million, and paid $38.5 million in cash in exchange for all of the outstanding capital stock and vested options and warrants of Pro Duct. We also assumed all outstanding unvested options to acquire Pro Duct common stock, which had a fair value of $2.5 million. The aggregate purchase price of $183.9 million included $5.2 million in acquisition related fees. No underwriters were involved in our issuance of common stock to the Pro Duct security holders, which we made 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 as of and for the year ended December 31, 2002 is derived from our consolidated financial statements audited by Deloitte & Touche LLP, independent

auditors, which are included elsewhere herein. The selected consolidated financial data set forth below for the years ended December 31, 2000 and 2001 and at December 31, 2001, which are included herein, and for each of the years ended December 31, 1998 and 1999 and at December 31, 1998, 1999 and 2000, which are not included herein, are derived from our consolidated financial statements audited by Arthur Andersen LLP, independent public accountants. 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, | | | | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2001 | 2002 |
| | (in thousands, except per share data) | | | | |
| **Statements of Operations Data:** | | | | | |
| Net sales | $ 44,264 | $ 81,100 | $142,065 | $220,993 | $236,493 |
| Cost of sales | 11,211 | 15,815 | 24,565 | 40,168 | 48,622 |
| Gross profit | 33,053 | 65,285 | 117,500 | 180,825 | 187,871 |
| Operating expenses: | | | | | |
| Research and development | 8,419 | 13,372 | 14,171 | 18,975 | 14,524 |
| In-process research and development (1) | — | — | — | 56,000 | — |
| Sales and marketing | 35,332 | 44,017 | 55,162 | 59,161 | 69,971 |
| General and administrative | 8,372 | 6,765 | 13,872 | 16,987 | 23,125 |
| Expenses related to terminated merger (2) | — | — | — | — | 5,705 |
| Total operating expenses | 52,123 | 64,154 | 83,205 | 151,123 | 113,325 |
| Income (loss) from operations | (19,070) | 1,131 | 34,295 | 29,702 | 74,546 |
| Other income, net (3) | 7,341 | 4,639 | 4,721 | 8,006 | 2,711 |
| Income (loss) before provision for income taxes | (11,729) | 5,770 | 39,016 | 37,708 | 77,257 |
| Provision for income taxes | — | 130 | 853 | 25,073 | 29,363 |
| Net income (loss) | $(11,729) | $ 5,640 | $ 38,163 | $ 12,635 | $ 47,894 |
| Net income (loss) per common and potential common share (4): | | | | | |
| Basic | $ (0.11) | $ 0.05 | $ 0.34 | $ 0.11 | $ 0.40 |
| Diluted | $ (0.11) | $ 0.05 | $ 0.32 | $ 0.10 | $ 0.39 |
| Weighted average common and potential common shares outstanding (4): | | | | | |
| Basic | 105,858 | 107,346 | 110,754 | 115,396 | 120,114 |
| Diluted | 105,858 | 112,530 | 117,960 | 120,776 | 122,782 |
| **Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and investment securities | $ 69,908 | $ 70,368 | $ 88,845 | $153,242 | $163,744 |
| Total assets | 97,737 | 112,328 | 170,886 | 386,760 | 361,626 |
| Retained (deficit) earnings | (80,908) | (75,268) | (37,105) | (24,470) | 23,424 |
| Total stockholders' equity | 85,807 | 94,991 | 147,046 | 350,308 | 324,728 |

(1) We incurred in-process research and development charges totaling approximately $56.0 million in 2001 related to our acquisition of Pro Duct.

(2) We incurred charges totaling approximately $5.7 million in 2002 related to our abandoned merger with Digene.

(3) We received other income of $3.1 million in both 1998 and 2001 from two separate litigation settlements.

(4) 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

Cytyc designs, develops, manufactures and markets a sample preparation system for medical diagnostic applications. Our 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 general, non-gynecological testing applications. The ThinPrep System, which was cleared for marketing as a replacement for the conventional Pap smear method for cervical cancer screening by the FDA in 1996, is designed to reduce the incidence of false negative diagnoses, improve slide quality, reduce inconclusive and inadequate slide samples and enable a single sample to be used for additional diagnostic testing.

### Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. A "critical accounting policy" is one which is both important to the portrayal of our financial conditions 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. We continuously evaluate our critical accounting policies and estimates, including those related to revenue recognition, valuation of long-lived assets, deferred taxes and the allowance for doubtful accounts. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

*Revenue recognition.* Our revenue recognition policy is significant because revenue is a key component of our results of operations. We follow very specific and detailed guidelines in measuring revenue; however, certain judgments affect the application of our revenue policy. For example, revenue is not recognized from sales transactions unless the collection of the resulting receivable is reasonably assured. We assess the likelihood of 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. Additionally, we do not recognize revenue from sales of processors when we have an obligation to perform installation and training which is deemed to be critical to the functionality of the processor (e.g. due to FDA requirements) until completion of the required installation and training. In instances where installation and training are not deemed to be critical to the functionality of the processor, we estimate and accrue the cost to provide such installation and training and recognize those costs when the related revenue is recognized. 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.* We assess 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, we 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, we ceased amortization of goodwill. This had the effect of eliminating goodwill amortization of $442,000 in our 2002 statement of income. In lieu of amortization, we are required to perform an impairment review annually, or earlier if indicators of potential impairment exist. Based on our

annual impairment review during 2002, the carrying amount of goodwill did not exceed its fair value and, accordingly, no impairment loss exists. We have determined that there are no indicators requiring further impairment review in 2002. At December 31, 2002, we have $108.7 million of intangible assets, of which $91.1 million represents goodwill. An impairment to our intangible assets could result in a material, non-cash expense in our consolidated statement of income. We have not recorded any impairment charges in any of the past three years. The carrying value of our net deferred tax assets assumes that we will be able to generate sufficient future taxable income in certain tax jurisdictions, based on estimates and assumptions, to fully recover the net carrying value of the assets. If these estimates, and related assumptions change in the future, we may be required to record additional valuation allowances against our deferred tax assets resulting in additional income tax expense in our consolidated statement of income.

*Allowance for Doubtful Accounts.* We perform ongoing credit evaluations of our customers and adjust credit limits based upon payment history and the customer's credit worthiness, as determined by our review of their current credit information. We continuously monitor collections and payments from our customers and maintain 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 our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates that we have 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 our 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 principles in the United States.

## Results of Operations

*Years Ended December 31, 2002 and 2001*

Net sales increased to $236.5 million in 2002 from $221.0 million for 2001, an increase of 7%. The increase was primarily due to increased sales of our ThinPrep Pap Test for cervical cancer screening in the United States, reflecting strong end user physician demand. The rate of growth in net sales decreased in 2002 compared to 2001 due primarily to changes in inventory management by some of our laboratory customers, which impacted their ordering patterns during 2002. Gross profit increased to $187.9 million in 2002 from $180.8 million for 2001, an increase of 4%. The gross margin decreased to 79% in 2002 as compared to 82% for 2001, primarily due to lower average selling prices in the first quarter of 2002 related to sales promotion discounts and to a lesser extent a larger percentage of total revenue with international customers who have lower average selling prices. We expect gross margin to continue to approximate 79% to 81% in 2003.

Total operating expenses decreased to $113.3 million in 2002 from $151.1 million for 2001, a decrease of 25%, largely due to a one-time charge of $56.0 million in 2001 to write off in-process research and development costs related to our acquisition of Pro Duct. Excluding the charges related to the Pro Duct acquisition in 2001 and costs related to the abandoned Digene merger of $5.7 million in 2002, total operating expenses would have increased 13%. Research and development costs decreased to $14.5 million in 2002 from $19.0 million for 2001, a decrease of 23%, primarily as a result of lower engineering costs associated with our ThinPrep Imaging System development activities. We expect to increase our expenditures in 2003 for research and development to fund follow-on studies of the FirstCyte Breast Test, as well as follow-on products and additional applications of ThinPrep technology. Sales and marketing costs increased to $70.0 million in 2002 from $59.2 million for 2001, an increase of 18%. This increase primarily reflects expenses associated with expansion of international subsidiaries, U.S. sales force meeting and travel expenses and personnel costs to develop the market and customer base for the FirstCyte Breast Test. General and administrative costs increased to $28.8 million in 2002 from $17.0 million for 2001, an increase of 70%, primarily due to the $5.7 million in costs related to the

abandoned Digene merger as well as a combination of increased personnel costs and professional fees in our infrastructure departments, which grew to support our business.

Interest income decreased to $3.5 million in 2002 from $5.4 million for 2001, a decrease of 35%, due primarily to lower interest rates. We also recorded $3.1 million during 2001 in other income relating to the settlement of the TriPath litigation.

Our effective tax rate for 2002 was 38%. Our effective tax rate for 2001 was 66.5%, due primarily to the nondeductible in process research and development charge related to the Pro Duct acquisition, partially offset by release of the valuation allowance related to certain of our net operating loss carryforwards and other deferred tax assets. We anticipate that our effective tax rate in 2003 will be 40% due to a reduction in research and development credits as a percentage of our taxable income.

*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 our 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 primarily due 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 our 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 the Pro Duct in-process research and development charge, 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 our 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, regional meetings and marketing programs. 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, 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. We recorded $3.1 million in 2001 as other income relating to the settlement of the TriPath litigation.

Our effective tax rate for 2001 was 66.5% which was higher than the then current combined federal and state statutory rate due primarily to the non deductible in process research and development charge related to the Pro Duct acquisition, partially offset by release of the valuation allowance related to certain of our net operating loss carryforwards and other deferred tax assets. Our effective tax rate was 2.1% in 2000, which was less than the then current combined federal and state statutory rates primarily as a result of utilization of our net operating loss carryforwards.

## Liquidity and Capital Resources

At December 31, 2002, we had cash, cash equivalents and investment securities totaling $163.7 million. Cash provided by operations was $98.0 million in 2002, compared to $91.7 million in 2001, primarily as a result of improved operating results in 2002 as well as lower accounts receivable caused by more consistent customer ordering patterns and improved collections.

Our investing activities used cash of $49.9 million in 2002, compared to $90.2 million in 2001. These investing activities included capital expenditures of $6.7 million and $9.2 million, respectively, primarily related

to the purchase of machinery and office equipment. At the same time, we invested cash of $43.0 million in 2002 for the net purchases of investment securities, compared to $54.0 million of such net investment purchases in 2001. Investing activities in 2001 included the purchase of Pro Duct for net cash of $25.8 million. During 2003, we expect to incur capital expenditures of approximately $16 million, which include improvements to certain of our manufacturing and distribution facilities as well as other machinery and equipment purchases to support the growth in our business.

Our financing activities in 2002 used cash of $81.8 million, primarily related to the repurchase of $92.7 million of our common stock, partially funded by proceeds from the exercise of common stock options. Our financing activities in 2001 generated cash of $9.8 million and consisted primarily of proceeds from the exercise of stock options. Our board of directors has authorized, in the aggregate, up to $150 million for the repurchase of shares of our common stock, plus the cost of purchasing additional shares in an amount equal to the number of shares issued to our stock option holders upon exercise of their stock options. Of the amounts authorized under the repurchase plan, $50 million, plus the cost of purchasing shares upon exercise of stock options, is available until January 2007; an additional $50 million is available until November 2007; and the remaining $50 million is available until December 2003. As of December 31, 2002, we have repurchased 9.6 million shares of our common stock for cash totaling $92.7 million, with an average price paid of $9.63 per share.

As of December 31, 2002, we had contractual cash obligations as follows (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| Contractual Obligations | Total | Less than 1 Year | 2-3 Years | 4-5 Years | After 5 Years |
| Operating Leases | $ 9,219 | $2,551 | $3,210 | $1,366 | $ 2,092 |
| Unconditional Purchase Obligations | 30,000 | 3,000 | 6,000 | 6,000 | 15,000 |
| Total Contractual Cash Obligations | $39,219 | $5,551 | $9,210 | $7,366 | $17,092 |

Our operating lease obligations relate primarily to our facilities, but also include certain automobiles and office equipment outside of the United States. These operating leases have expiration dates ranging from 2003 through 2013. In addition to operating leases, we have also entered into certain long term supply contracts with terms of up to 10 years to assure continuity of supply of certain key components and raw materials while maintaining high quality and reliability. In certain of these contracts, a minimum purchase commitment has been established.

We expect that our cash and cash equivalents, investment securities and cash flows from operating activities will be sufficient to meet our projected operating cash needs, including capital expenditures, lease and purchase commitments, tax payments and other strategic initiatives.

### Off-Balance Sheet Arrangements

We do not maintain any off-balance sheet financing arrangements apart from the operating leases described above.

### Income Taxes

We have net operating loss carryforwards for federal income tax purposes of approximately $16.3 million at December 31, 2002 that will expire at various dates through the year 2020, if not utilized. The net operating loss 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.

We have research and development tax credit carryforwards for state tax purposes of $3.4 million.

## Item 7A. Quantitative and Qualitative Disclosures About Market Risk

*Derivative Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments.* We do not participate in derivative financial instruments, other financial instruments for which the fair value disclosure would be required under SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, or derivative commodity instruments. All of our investments are in short-term, investment-grade commercial paper, corporate bonds, certificates of deposit and U.S. Government and agency securities that are carried at fair value on our books. Accordingly, we have no quantitative information concerning the market risk of participating in such investments.

*Primary Market Risk Exposures.* Our primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. Our investment portfolio of cash equivalents and investment securities is subject to interest rate fluctuations, but we believe this risk is immaterial due to the short-term nature of these investments. Our business outside the United States is conducted in local currency. We have no foreign exchange contracts, option contracts, or other foreign hedging arrangements. We estimate that any market risk associated with our foreign operations is not significant and is unlikely to have a material adverse effect on our business, financial condition or 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-26 of this Form 10-K.

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

Effective as of May 21, 2002, our board of directors dismissed Arthur Andersen LLP as our independent accountants. For each of the fiscal years ended December 31, 2000 and 2001 and through the date of their dismissal, the former auditors did not disagree with us on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure which disagreements, if not resolved to their satisfaction, would have caused them to make reference thereto in their report on the financial statements for such years. During the period from our inception to the date of their dismissal, there have been no reportable events as defined in Regulation S-K Item 304. Neither of Arthur Andersen LLP's accountants' reports for either of the past two years contained an adverse opinion or disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope or accounting principles. In response to our request, Arthur Andersen LLP has furnished us with a letter addressed to the SEC stating whether Arthur Andersen LLP agrees with the above statements. We have filed with the SEC a copy of such letter dated May 28, 2002 as Exhibit 16 to our Current Report on Form 8-K on May 28, 2002. On May 21, 2002, the audit committee recommended, and our board of directors approved, Deloitte & Touche LLP as our independent public accountants. Prior to retaining Deloitte & Touche LLP, we had not consulted with Deloitte & Touche LLP on any accounting, auditing or reporting matters.

## PART III

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

The information required under this item may be found under "Executive Officers of Cytyc Corporation" in Part I, Item 1—"Business" of this Annual Report on Form 10-K, as well as under the sections captioned "Election of Directors", "Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement (the "2003 Proxy Statement"), which will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2002, 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 2003 Proxy Statement, and is incorporated herein by reference.

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

#### Equity Compensation Plan Information

We offer various employee and director equity compensation plans, including the 1995 Stock Plan, the 1995 Non-Employee Director Stock Option Plan, the 2001 Non-Employee Director Stock Plan and the 1989 Stock Plan. Our primary stock plan, the 1995 Stock Plan, provides for the grant of various incentives, including nonqualified and incentive stock options, stock awards, and opportunities to make direct purchases of our common stock. The aggregate number of shares of common stock that may be issued pursuant to the 1995 Stock 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 Stock Plan, subject to certain adjustments.

All of our equity compensation plans have been approved by our stockholders. We do not have any warrants or stock appreciation rights outstanding under our equity compensation plans. The following table summarizes information about our equity compensation plans at December 31, 2002:

| Number of Shares to be Issued Upon Exercise of Outstanding Stock Options | Weighted Average Exercise price per share | Number of Shares Available for Future Issuance |
|---|---|---|
| 19,389,667 | $16.24 | 5,358,464 |

Additional information required under this item may be found under the section captioned "Securities Ownership of Certain Beneficial Owners and Management" in the 2003 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 2003 Proxy Statement, and is incorporated herein by reference.

### Item 14. Controls and Procedures

(a) *Disclosure Controls and Procedures.* Within the 90-day period prior to the filing date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our

Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective in timely notification to them of information we are required to disclose in our periodic SEC filings and in ensuring that this information is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations.

(b) *Internal Controls.* There have been no significant changes in our internal controls or in other factors that could significantly affect those controls, including any corrective actions with regard to significant deficiencies and material weaknesses, subsequent to the date of their evaluation.

(c) *Limitations on the Effectiveness of Controls.* The company's management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our Disclosure Controls or our Internal Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Some inherent limitations in all control systems include the realities that (i) judgments in decision-making can be faulty; (ii) breakdowns can occur because of simple error or mistake; (iii) controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control; and (iv) the design of any system of controls is based in part upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## PART IV

### Item 15. 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(9) | Agreement and Plan of Merger, dated October 17, 2001, by and among Cytyc Corporation, Pro Duct Health, Inc., and Cytyc Health Corporation. |
| 2.2(10) | Amendment to Agreement and Plan of Merger, dated as of November 30, 2001, by and among Cytyc Corporation, Pro Duct Health Inc., and Cytyc Health Corporation. |
| 2.3(11) | Agreement and Plan of Merger, dated as of February 19, 2002, by and among Cytyc Corporation, Digene Corporation, and Cruiser, Inc. |
| 3.1(2) | Third Amended and Restated Certificate of Incorporation of Cytyc Corporation. |
| 3.2(2) | Amended and Restated By-Laws of Cytyc Corporation. |
| 3.3(7) | Certificate of Amendment of Third Amended and Restated Certificate of Incorporation. |
| 4.1(1) | Specimen certificate representing the Common Stock. |
| 4.2(3) | Rights Agreement, dated as of August 27, 1997, between Cytyc 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 Cytyc 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(8)* | Amended and Restated 1995 Non-Employee Director Stock Option Plan. |
| 10.5(12)* | 1995 Employee Stock Purchase Plan, as amended. |
| 10.6(1)# | License Agreement between Cytyc Corporation and DEKA Products Limited Partnership dated March 22, 1993. |
| 10.7(1) | Form of Indemnification Agreement. |
| 10.8(1) | Lease Agreement between Cytyc Corporation 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 Cytyc Corporation and BFA Realty Partnership, L.P. d/b/a BFA, Limited Partnership. |

| Exhibit Number | Description |
|---|---|
| 10.10(6)* | Amended and Restated Cytyc Corporation Director Deferred Compensation Plan. |
| 10.11(13)* | 2001 Non-Employee Director Stock Plan. |
| 10.12(14)* | Pro Duct Health, Inc. 1998 Stock Plan. |
| 10.13tt## | Supply Agreement between Cytyc Corporation, Whatman, Inc. and Whatman SA dated as of December 31, 2000, as amended October 16, 2001 and May 2, 2002 |
| 10.14tt## | Master Agreement between Cytyc Corporation and Laboratory Corporation of America Holdings dated February 1, 2000, as amended December 20, 2001 |
| 10.15tt | Form of Change of Control Agreement entered between Cytyc Corporation and certain executive officers dated as of July 30, 2002. |
| 21.1tt | List of Our Subsidiaries. |
| 23.1tt | Consent of Deloitte & Touche LLP. |
| 24.1tt | Power of Attorney (see signature page hereto). |
| 99.1tt | Statement of Patrick J. Sullivan, Chief Executive Officer and President, pursuant to 18 U.S.C. Section 1350. |
| 99.2tt | Statement of Robert L. Bowen, Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350. |

(1) Incorporated herein by reference to the exhibits to our Registration Statement on Form S-1 (File No. 333-00300).
(2) Incorporated by reference to the exhibits to our Registration Statement on Form S-1 (File No. 333-19367).
(3) Incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed August 29, 1997.
(4) Incorporated herein by reference to Exhibit 4.2 to our Quarterly Report on Form 10-Q, filed August 13, 1998.
(5) Incorporated herein by reference to Exhibit 10.9 to our Annual Report on Form 10-K, filed March 31, 1998.
(6) Incorporated herein by reference to Exhibit 10.12 to our Annual Report on Form 10-K, filed March 31, 1999.
(7) Incorporated herein by reference to Exhibits 3, 4 to our Quarterly Report on Form 10-Q, filed August 14, 2000.
(8) Incorporated herein by reference to Exhibit 10 to our Quarterly Report on Form 10-Q, filed August 14, 2000.
(9) Incorporated herein by reference to the Exhibits to our Current Report on Form 8-K, filed October 19, 2001.
(10) Incorporated herein by reference to the Exhibits to our Current Report on Form 8-K, filed December 14, 2001.
(11) Incorporated herein by reference to the Exhibits to our Current Report on Form 8-K, filed February 20, 2002.
(12) Incorporated herein by reference to Exhibit 10.5 to our Registration Statement on Form S-1 (File No. 333-00300) and Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed August 8, 2001.
(13) Incorporated herein by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed August 8, 2001.
(14) Incorporated herein by reference to Exhibit 4 to our 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
tt Filed herewith.
\# Confidential treatment granted as to certain portions.
## Confidential treatment requested as to certain portions.

(b) *Reports On Form 8-K*

We filed one report on Form 8-K filed during the quarter ended December 31, 2002.

On December 18, 2002, we filed a current report on Form 8-K to disclose that a purported securities class action lawsuit was filed on December 13, 2002, in the United States District Court for the District of Massachusetts against us and two of our officers. We filed the press release announcing this lawsuit as an exhibit to such Form 8-K.

Subsequent 8-K filings

On January 17, 2003, we filed a current report on Form 8-K to disclose that our board of directors authorized an additional $50 million for our stock repurchase program. We filed the press release announcing this increase as an exhibit to such Form 8-K.

On March 5, 2003, we filed a current report on Form 8-K to disclose that the Scottish Cervical Screening Programme has selected the ThinPrep Pap Test as the new technology for total conversion of all cervical screening centers in Scotland. We filed the press release announcing this increase as an exhibit to such Form 8-K.

(c) *Exhibits*

We hereby file 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. 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 24, 2003

By: /s/ PATRICK J. SULLIVAN
Patrick J. Sullivan
Chief Executive Officer and President

## POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Cytyc 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 Cytyc 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.

| Signature | Title(s) | Date |
|---|---|---|
| /s/ PATRICK J. SULLIVAN<br>Patrick J. Sullivan | Chief Executive Officer (Principal Executive Officer), President, and Chairman of the Board of Directors | March 24, 2003 |
| /s/ ROBERT L. BOWEN<br>Robert L. Bowen | Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer) | March 24, 2003 |
| /s/ WALTER E. BOOMER<br>Walter E. Boomer | Director | March 24, 2003 |
| /s/ MARC C. BRESLAWSKY<br>Marc C. Breslawsky | Director | March 24, 2003 |
| /s/ SALLY W. CRAWFORD<br>Sally W. Crawford | Director | March 24, 2003 |
| /s/ WILLIAM G. LITTLE<br>William G. Little | Director | March 24, 2003 |

| Signature | Title(s) | Date |
|---|---|---|
| /s/ WILLIAM H. LONGFIELD<br>William H. Longfield | Director | March 24, 2003 |
| /s/ JOSEPH B. MARTIN, M.D., Ph.D<br>Joseph B. Martin, M.D., Ph.D | Director | March 24, 2003 |
| /s/ WILLIAM MCDANIEL<br>William McDaniel | Vice Chairman of the Board of Directors | March 24, 2003 |
| /s/ ANNA S. RICHO<br>Anna S. Richo | Director | March 24, 2003 |

## CERTIFICATIONS

I, Patrick J. Sullivan, certify that:

1. I have reviewed this annual report on Form 10-K of Cytyc Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   (c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 24, 2003

/s/ PATRICK J. SULLIVAN

**Patrick J. Sullivan**
**Chief Executive Officer and President**

I, Robert L. Bowen, certify that:

1. I have reviewed this annual report on Form 10-K of Cytyc Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   (c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 24, 2003

/s/ ROBERT L. BOWEN

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

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CYTYC CORPORATION

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

## INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of
Cytyc Corporation:

We have audited the accompanying consolidated balance sheet of Cytyc Corporation and subsidiaries (the "Company") as of December 31, 2002, and the related consolidated statements of income, stockholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. The Company's consolidated financial statements as of December 31, 2001 and for the years ended December 31, 2001 and 2000, were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those consolidated financial statements in their report dated January 21, 2002.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. 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 audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2002, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the Consolidated Financial Statements, on January 1, 2002, the Company adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets." As described above, the consolidated financial statements of Cytyc Corporation as of December 31, 2001, and for the years ended December 31, 2001 and 2000, were audited by other auditors who have ceased operations. These financial statements have been revised to include the transitional disclosures required by SFAS No. 142. Our audit procedures with respect to the disclosures in Note 2 with respect to 2001 and 2000 included (i) agreeing the previously reported net income to the previously issued financial statements and the adjustments to reported net income representing amortization expense recognized in those periods related to goodwill to the Company's underlying records obtained from management, and (ii) testing the mathematical accuracy of the reconciliation of adjusted net income to reported net income, and the related earnings per share amounts. In our opinion, the disclosures for 2001 and 2000 in Note 2 are appropriate. However, we were not engaged to audit, review, or apply any procedures to the 2001 and 2000 financial statements of the Company other than with respect to such disclosures and, accordingly, we do not express an opinion or any other form of assurance on the 2001 and 2000 financial statements taken as a whole.

DELOITTE & TOUCHE LLP

Boston, Massachusetts
January 27, 2003

**This is a copy of a report previously issued by Arthur Andersen LLP. This report has not been reissued by Arthur Andersen LLP nor has Arthur Andersen LLP provided a consent to the inclusion of its report in these financial statements. The financial statements as of December 31, 2000 and for the year ended December 31, 1999 are not presented herein.**

## REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Stockholders and Board of Directors of
Cytyc Corporation:

We have audited the accompanying consolidated balance sheets of Cytyc 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 Cytyc 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, 2001 | December 31, 2002 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 71,928 | $ 39,251 |
| Investment securities | 81,314 | 124,493 |
| Accounts receivable, net of allowance of $1,987 and $2,103 at December 31, 2001 and 2002, respectively | 50,278 | 34,066 |
| Inventories | 10,698 | 11,012 |
| Prepaid expenses and other current assets | 1,583 | 2,046 |
| Total current assets | 215,801 | 210,868 |
| Property and equipment, net | 26,662 | 27,281 |
| Intangible assets: | | |
| Patented technology, net of accumulated amortization of $219 and $227 at December 31, 2001 and 2002, respectively | 211 | 203 |
| Developed technology and know-how, net of accumulated amortization of $122 and $1,583 at December 31, 2001 and 2002, respectively | 18,878 | 17,417 |
| Goodwill | 94,881 | 91,097 |
| Total intangible assets | 113,970 | 108,717 |
| Deferred tax assets, net | 23,485 | 8,343 |
| Other assets, net | 6,842 | 6,417 |
| Total assets | $386,760 | $361,626 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 9,325 | $ 7,106 |
| Accrued expenses | 24,789 | 26,711 |
| Deferred revenue | 1,501 | 2,768 |
| Total current liabilities | 35,615 | 36,585 |
| Non-current liabilities | 837 | 313 |
| Commitments and contingencies (Note 9) | | |
| 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—121,355,344 and 123,179,055 in 2001 and 2002, respectively Outstanding—121,355,344 and 113,555,378 in 2001 and 2002, respectively | 1,214 | 1,232 |
| Additional paid-in capital | 376,092 | 392,253 |
| Treasury stock, at cost: 9,623,677 shares in 2002 | — | (92,717) |
| Deferred compensation | (999) | (240) |
| Accumulated other comprehensive (loss) income | (1,529) | 776 |
| Retained (deficit) earnings | (24,470) | 23,424 |
| Total stockholders' equity | 350,308 | 324,728 |
| Total liabilities and stockholders' equity | $386,760 | $361,626 |

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

CYTYC CORPORATION

CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share amounts)

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Net sales | $142,065 | $220,993 | $236,493 |
| Cost of sales | 24,565 | 40,168 | 48,622 |
| Gross profit | 117,500 | 180,825 | 187,871 |
| Operating expenses: | | | |
| Research and development | 14,171 | 18,975 | 14,524 |
| In-process research and development | — | 56,000 | — |
| Sales and marketing | 55,162 | 59,161 | 69,971 |
| General and administrative | 13,872 | 16,987 | 23,125 |
| Expenses related to terminated merger (Note 4(c)) | — | — | 5,705 |
| Total operating expenses | 83,205 | 151,123 | 113,325 |
| Income from operations | 34,295 | 29,702 | 74,546 |
| Other income, net: | | | |
| Interest income | 4,734 | 5,412 | 3,505 |
| Other income (expense) | (13) | (493) | (794) |
| Litigation settlement | — | 3,087 | — |
| Total other income, net | 4,721 | 8,006 | 2,711 |
| Income before provision for income taxes | 39,016 | 37,708 | 77,257 |
| Provision for income taxes | 853 | 25,073 | 29,363 |
| Net income | $ 38,163 | $ 12,635 | $ 47,894 |
| Net income per common and potential common share: | | | |
| Basic | $ 0.34 | $ 0.11 | $ 0.40 |
| Diluted | $ 0.32 | $ 0.10 | $ 0.39 |
| Weighted average common and potential common shares outstanding: | | | |
| Basic | 110,754 | 115,396 | 120,114 |
| Diluted | 117,960 | 120,776 | 122,782 |

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 Number of Shares | Common Stock Value | Additional Paid-in Capital | Treasury Stock | Deferred Compensation | Accumulated Other Comprehensive Income(Loss) | Retained (Deficit) Earnings | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|
| 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 loss, net— | | | | | | | | | |
| Unrealized gain on securities | 165 | — | — | — | — | — | 165 | — | 165 |
| Translation adjustments | (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 loss, net— | | | | | | | | | |
| Unrealized gain on securities | 98 | — | — | — | — | — | 98 | — | 98 |
| Translation adjustments | (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 |
| Exercise of common stock options | — | 1,696,817 | 17 | 9,735 | — | — | — | — | 9,752 |
| Issuance of shares under Employee Stock Purchase Plan | — | 108,411 | 1 | 1,166 | — | — | — | — | 1,167 |
| Issuance of shares under Directors' and Executive Stock Plans | — | 18,483 | — | 306 | — | — | — | — | 306 |
| Repurchase of 9,623,677 shares of common stock | — | — | — | — | (92,717) | — | — | — | (92,717) |
| Stock-based compensation to consultant and related amortization | — | — | — | 281 | — | (198) | — | — | 83 |
| Amortization of and adjustments to deferred compensation for Pro Duct stock options | — | — | — | (615) | — | 957 | — | — | 342 |
| Tax benefit from stock options exercised | — | — | — | 5,288 | — | — | — | — | 5,288 |
| Comprehensive income— | | | | | | | | | |
| Net income | $47,894 | — | — | — | — | — | — | 47,894 | 47,894 |
| Other comprehensive income— | | | | | | | | | |
| Unrealized gain on securities | 141 | — | — | — | — | — | 141 | — | 141 |
| Translation adjustments | 2,164 | — | — | — | — | — | 2,164 | — | 2,164 |
| Comprehensive income | $50,199 | — | — | — | — | — | — | — | — |
| Balance, December 31, 2002 | | 123,179,055 | $1,232 | $392,253 | $(92,717) | $ (240) | $776 | $ 23,424 | $324,728 |

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, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| **Cash flows from operating activities:** | | | |
| Net income | $ 38,163 | $ 12,635 | $ 47,894 |
| Adjustments to reconcile net income to net cash provided by operating activities | | | |
| Depreciation and amortization | 3,460 | 4,852 | 7,717 |
| Provision for doubtful accounts | 656 | 567 | 468 |
| Amortization of warrant | 1,465 | 2,499 | 1,205 |
| 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 | 241 | 445 | 389 |
| Compensation expense related to stock options assumed in acquisition | — | 55 | 342 |
| Change in deferred tax asset | — | (20,540) | 15,142 |
| Changes in assets and liabilities, excluding effects of acquisition— | | | |
| Accounts receivable | (18,050) | (10,549) | 17,613 |
| Inventories | (5,388) | 598 | (340) |
| Prepaid expenses and other current assets | (139) | (639) | (558) |
| Accounts payable | 1,188 | 2,829 | (3,125) |
| Accrued expenses | 3,966 | 5,156 | 4,711 |
| Deferred revenue | 355 | (576) | 1,263 |
| Tax benefit from exercise of stock options | — | 41,053 | 5,288 |
| Net cash provided by operating activities | 25,917 | 91,673 | 98,009 |
| **Cash flows from investing activities:** | | | |
| Acquisition of Acu-Pak, Inc., net of cash acquired | (5,760) | — | — |
| Acquisition of Pro•Duct Health Inc., net of cash acquired | — | (25,791) | — |
| Decrease (increase) in other assets | 651 | (1,147) | (162) |
| Purchases of property and equipment. | (10,813) | (9,248) | (6,657) |
| Purchases of investment securities | (49,803) | (156,293) | (156,469) |
| Proceeds from sale of investment securities | 63,259 | 102,317 | 113,431 |
| Net cash used in investing activities | (2,466) | (90,162) | (49,857) |
| **Cash flows from financing activities:** | | | |
| Proceeds from exercise of stock options and warrants | 8,367 | 8,741 | 9,752 |
| Proceeds from issuance of shares under Employee Stock Purchase Plan | 694 | 1,066 | 1,167 |
| Purchase of treasury shares | — | — | (92,717) |
| Net cash provided by (used in) financing activities | 9,061 | 9,807 | (81,798) |
| Effect of exchange rate changes on cash | (593) | (995) | 969 |
| Net increase (decrease) in cash and cash equivalents | 31,919 | 10,323 | (32,677) |
| Cash and cash equivalents, beginning of year | 29,686 | 61,605 | 71,928 |
| Cash and cash equivalents, end of year | $ 61,605 | $ 71,928 | $ 39,251 |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid for income taxes | $ 442 | $ 1,866 | $ 3,542 |
| Supplemental disclosure of non-cash items: | | | |
| Unrealized holding gain on investment securities | $ 165 | $ 98 | $ 141 |
| Issuance of common stock warrant to Quest Diagnostics, Inc | $ 5,169 | $ 5 | $ — |
| Issuance of shares under director's and executive stock plans | $ 241 | $ 393 | $ 306 |
| Issuance of common stock to non-employees for services | $ — | $ 52 | $ — |
| 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: | | | |
| 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 | $ 994 | $ 5,203 | $ — |

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

## (1) The Company

Cytyc 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 general, 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 general, 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.

On November 30, 2001, the Company acquired Pro•Duct Health Inc. ("Pro Duct"), a privately held company that developed a ductal lavage device to enhance the evaluation of risk for breast cancer. Using this technology, the Company introduced the FirstCyte Breast Test through its Cytyc Health Corporation subsidiary.

## (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 the consolidated financial statements. 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 net sales 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. All intercompany transactions and balances have been eliminated in consolidation.

### *(b) Foreign Currency Translation*

The accounts of the Company's foreign subsidiaries are translated in accordance with Statement of Financial Accounting Standards ("SFAS") No. 52, *Foreign Currency Translation*. The Company has determined that the functional currency of its subsidiaries should be the local currency. 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. 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. Foreign currency transaction gains or losses are recorded immediately to income. The Company had realized and unrealized net foreign currency transaction losses of approximately $16,000, $192,000 and $847,000 in 2000, 2001 and 2002, respectively.

### *(c) 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. Financial instruments that potentially subject the Company to concentrations of credit risk are principally cash, cash equivalents, investment securities 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. As of December 31, 2001 and 2002, the accounts receivable balance from one customer represented approximately 20% and 11% of the Company's accounts receivable portfolio.

*(d) Dependence on Single Source Suppliers*

Certain key components of the ThinPrep System, including its proprietary filter material, and the FirstCyte Breast Test 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.

*(e) Cash and Cash Equivalents*

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

*(f) Investment Securities*

The Company follows the provisions of SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The Company has classified its investment 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 (loss) income in stockholders' equity (see Note 2 (s)).

At December 31, 2002, the Company's available-for-sale debt securities had contractual maturities that expire at various dates through November 2004. 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, 2002 and 2001, the amortized cost basis, aggregate fair value, gross unrealized holding gains and average months to maturity by major security type are as follows:

| | Amortized Cost | Gross Unrealized Holding Gains | Fair Value |
|---|---|---|---|
| | | (in thousands) | |
| **December 31, 2002** | | | |
| U.S. Government and Agency securities (average maturity of 3.4 months) | $ 86,431 | $180 | $ 86,611 |
| Corporate Bonds (average maturity of 8.5 months) | 31,898 | 60 | 31,958 |
| Commercial Paper (average maturity of 4.5 months) | 895 | — | 895 |
| Certificates of Deposit (average maturity of 5.1 months) | 5,015 | 14 | 5,029 |
| | $124,239 | $254 | $124,493 |
| **December 31, 2001** | | | |
| 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) | 2,889 | 1 | 2,890 |
| | $ 81,201 | $113 | $ 81,314 |

*(g) Allowance for Doubtful Accounts*

The Company maintains reserves for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. These reserves are determined based upon historical experience and any specific customer collection issues that have been identified. Historically, the Company has not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area.

*(h) Inventories*

Inventories are stated at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of materials, labor and manufacturing overhead.

*(i) Property and Equipment*

Property and equipment is stated at cost, less accumulated 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:

| Asset Classification | Estimated Useful Life |
|---|---|
| Equipment | 3-7 Years |
| Furniture, fixtures and computer equipment | 2-7 Years |
| Building | 40 Years |
| Leasehold improvements | Life of lease |

*(j) Intangible Assets*

In June 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 142 requires that goodwill and intangible assets with indefinite lives no longer be amortized but, instead, be measured for impairment at least annually, or whenever events indicate that there may be an impairment. Other identifiable intangible assets will continue to be amortized over their estimated useful lives and reviewed for impairment if circumstances warrant.

On January 1, 2002, the Company adopted SFAS No. 142, as required, which resulted in no adjustment to the carrying amount of goodwill. The Company has selected July in which to perform its annual evaluation of goodwill for impairment. As of July 31, 2002, it was determined that the carrying amount of goodwill did not exceed its fair value and, accordingly, no impairment loss exists. There were no indicators of impairment subsequent to this annual review to require further assessment. The Company's other intangible assets, patented technology and developed technology and know-how, will continue to be amortized over their estimated useful lives of 25 years and 13 years, respectively. Impairment of these other intangible assets is determined as described in Note 2(1).

Adoption of SFAS No. 142 had the effect of reducing annual amortization expense of goodwill by approximately $450,000 in 2002.

Had the provisions of SFAS No. 142 been applied for the years ended December 31, 2000 and 2001, the Company's net income and net income per share would have been as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| | (in thousands, except per share data) | | |
| Reported net income | $38,163 | $12,635 | $47,894 |
| Goodwill amortization, net of tax | 433 | 148 | — |
| Adjusted net income | $38,596 | $12,783 | $47,894 |
| Diluted net income per common and potential common share: | | | |
| As reported | $ 0.32 | $ 0.10 | $ 0.39 |
| As adjusted | $ 0.33 | $ 0.11 | $ 0.39 |

Estimated amortization expense related to identifiable intangible assets that will continue to be amortized is as follows:

| | Amount |
|---|---|
| | (in thousands) |
| 2003 | $ 1,470 |
| 2004 | 1,470 |
| 2005 | 1,470 |
| 2006 | 1,470 |
| 2007 | 1,470 |
| Thereafter | 10,270 |
| Total | $17,620 |

The following table summarizes the Company's intangible assets:

| | Gross Carrying Amount | Accumulated Amortization | Net |
|---|---|---|---|
| | | (in thousands) | |
| **December 31, 2002** | | | |
| Amortizable intangible assets: | | | |
| Patented technology | $ 430 | $ 227 | $ 203 |
| Acquired developed technology and know-how | 19,000 | 1,583 | 17,417 |
| Total amortizable intangible assets | 19,430 | 1,810 | 17,620 |
| Goodwill | 91,097 | — | 91,097 |
| | $110,527 | $1,810 | $108,717 |
| **December 31, 2001** | | | |
| Amortizable intangible assets: | | | |
| Patented technology | $ 430 | $ 219 | $ 211 |
| Acquired developed technology and know-how | 19,000 | 122 | 18,878 |
| Total amortizable intangible assets | 19,430 | 341 | 19,089 |
| Goodwill | 94,881 | — | 94,881 |
| | $114,311 | $ 341 | $113,970 |

The following presents activity for goodwill:

| | 2001 | 2002 |
|---|---|---|
| | (in thousands) | |
| Balance, beginning of year | $ 2,670 | $94,881 |
| Acquisition of Pro Duct (see note 4(b)) | 92,653 | — |
| Amortization | (442) | — |
| Adjustments (see note 4(b)) | — | (3,784) |
| Balance, end of year | $94,881 | $91,097 |

*(k) Other Assets*

Other assets consist primarily of the value of TriPath Imaging, Inc. common shares and a related receivable (see Note 9 (d)) and ThinPrep Processors under sales-type leases or rental arrangements with customers.

*(l) Long-lived Assets*

In August 2001, the FASB issued SFAS No. 144, Accounting for Impairment or Disposal of Long-Lived Assets, which supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed of,* and the accounting and reporting provisions of Accounting Principles Board Opinion ("APB") No. 30, *Reporting the Results of Operations—Report the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions.* SFAS No. 144 requires 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 adoption of this statement in 2002 did not have a material impact on the Company's financial position or results of operations.

*(m) Product Warranty Obligation*

The Company records a liability for product warranty obligations at the time of sale based upon historical warranty experience. The term of the warranty is generally twelve months. The Company also records an additional liability for specific warranty matters when they become known and are reasonably estimable. The Company's product warranty obligations are included in accrued expenses.

*(n) Revenue Recognition*

The Company follows the provisions of Staff Accounting Bulletin No. 101, *Revenue Recognition.* Accordingly, the Company generally recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the sales price is fixed or determinable, and collectibility of the resulting receivable is reasonably assured The Company recognizes revenue on product sales of both processors and disposable supplies either upon shipment or upon delivery, depending on the shipping terms of the transaction and when delivery is deemed to have occurred. Provisions for estimated discounts and rebates are recorded as a reduction of net sales in the same period revenue is recognized. For processor sales where the Company is obligated to perform installation and training that is deemed critical to the functionality of the processor, revenue is deferred until after installation and training have occurred. Alternatively, when installation and training are not deemed critical to the functionality of the processor, the Company estimates and accrues the cost to provide the installation and training, and recognizes this amount when the related revenue is recognized.

Revenue from sales of service contracts are deferred and recognized ratably over the service period. The Company also rents processors to customers. Revenues from rental agreements are recorded over the term of the rental agreement.

*(o) Research and Development Costs*

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

*(p) 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 anticipated to be in effect when these differences reverse.

*(q) 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 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. 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, 2000, 2001 and 2002.

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| | (in thousands) | | |
| Basic weighted average common shares outstanding | 110,754 | 115,396 | 120,114 |
| Dilutive effect of assumed exercise of stock options and warrant | 7,206 | 5,380 | 2,668 |
| Weighted average common shares outstanding assuming dilution | 117,960 | 120,776 | 122,782 |

Diluted weighted average shares outstanding excludes 317,006, 244,079 and 11,700,422 potential common shares from stock options and warrant outstanding for the years ended December 31, 2000, 2001 and 2002, respectively, as their effect would be anti-dilutive. The warrant was exercised on June 6, 2001.

*(r) Stock-Based Compensation*

SFAS No. 123, *Accounting for Stock-Based Compensation*, addresses the financial accounting and reporting standards for stock or other equity-based compensation arrangements. The Company has elected to continue to use the intrinsic value-based method to account for employee stock option awards under the provisions of APB Opinion No. 25 and provides disclosures based on the fair value method in the notes to the financial statements (Note 8) as permitted by SFAS No. 123. Stock or other equity-based compensation for non-employees must be accounted for under the fair value-based method as required by SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and other related interpretations. Under this method, the equity-based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which is usually the vesting period.

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

| | December 31 | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| | (in thousands, except per share data) | | |
| Net income, as reported | $ 38,163 | $ 12,635 | $ 47,894 |
| Assumed stock compensation cost, net of tax | (16,713) | (39,384) | (54,240) |
| Pro forma net income (loss) | $ 21,450 | $(26,749) | $ (6,346) |
| Net income per common and potential common share: | | | |
| Basic—as reported | $ 0.34 | $ 0.11 | $ 0.40 |
| Basic—pro forma | $ 0.19 | $ (0.23) | $ (0.05) |
| Diluted—as reported | $ 0.32 | $ 0.10 | $ 0.39 |
| Diluted—pro forma | $ 0.18 | $ (0.23) | $ (0.05) |

The weighted average fair market value of the stock options as of the date of grant for the years ended December 31, 2000, 2001 and 2002, was $12.72, $17.37 and $11.49, respectively.

The underlying assumptions used in the Black Scholes model are as follows:

| | December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Risk-free interest rate | 6.07% | 4.49% | 3.81% |
| Expected dividend yield | — | — | — |
| Expected lives | 5.00 | 5.00 | 5.00 |
| Expected volatility | 105% | 96% | 92% |

*(s) 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:

| | Cumulative Translation Adjustment | Unrealized Gain (Loss) on Available-for-sale Securities | Accumulated Other Comprehensive Income (Loss) |
|---|---|---|---|
| | | (in thousands) | |
| 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 | (1,642) | 113 | (1,529) |
| Current period change | 2,164 | 141 | 2,305 |
| Balance as of December 31, 2002 | $ 522 | $ 254 | $ 776 |

*(t) 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. Substantially all of the Company's assets are located within

the United States. During 2000, 2001 and 2002, the Company derived its sales from the following geographies (as a percentage of net sales):

| | Years Ended | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| United States | 92% | 93% | 92% |
| Rest of World | 8% | 7% | 8% |
| | 100% | 100% | 100% |

In 2000 and 2001, sales to one customer represented approximately 19%, and 20%, respectively, of net sales. In 2002, sales to two customers represented approximately 20%, and 13% respectively, of net sales.

*(u) Recent Accounting Pronouncements*

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure, an amendment of FASB Statement No. 123.* This Statement amends FASB Statement No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of Statement No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. Management has determined that it will continue to account for stock-based compensation to employees under the provisions of APB No. 25 and will make all required disclosures in its financial reports.

In November 2002, the FASB issued Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* ("FIN 45"). FIN 45 elaborates on the existing disclosure requirements for most guarantees. FIN 45 requires that at the time a company issues certain guarantees, the company must recognize an initial liability for the fair value, or market value, of the obligations it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. FIN 45's disclosure requirements are effective for financial statements of interim or annual periods ending on or after December 31, 2002 and are applicable to all guarantees issued by the guarantor subject to FIN 45's scope, including guarantees issued prior to the issuance of FIN 45. The adoption of the disclosure requirements of FIN 45 did not have a material impact on the Company's consolidated financial position or results of operations. The Company is currently assessing the impact of the initial recognition and initial measurement requirements of FIN 45.

## (3) Other Balance Sheet Information

Components of selected captions in the consolidated balance sheets at December 31 consisted of:

| | 2001 | 2002 |
|---|---|---|
| | (in thousands) | |
| Inventories | | |
| Raw materials and work-in-process | $ 6,377 | $ 7,388 |
| Finished goods | 4,321 | 3,624 |
| | $10,698 | $11,012 |
| Property and Equipment | | |
| Equipment | $ 9,105 | $15,612 |
| Furniture, fixtures and computer equipment | 11,835 | 13,628 |
| Leasehold improvements | 6,600 | 8,479 |
| Land | 579 | 579 |
| Building | 1,872 | 1,872 |
| Construction-in-process | 9,749 | 6,425 |
| | 39,740 | 46,595 |
| Less—accumulated depreciation and amortization | 13,078 | 19,314 |
| | $26,662 | $27,281 |
| Accrued Expenses | | |
| Accrued compensation | $ 8,334 | $ 9,207 |
| Accrued sales and marketing | 3,726 | 4,622 |
| Accrued sales and VAT taxes | 5,133 | 6,348 |
| Accrued product warranty | 699 | 1,923 |
| Accrued royalties | 699 | 1,397 |
| Other accruals | 6,198 | 3,214 |
| | $24,789 | $26,711 |

Changes in the product warranty obligations for the years ended December 31, 2001 and 2002 are as follows:

| | 2001 | 2002 |
|---|---|---|
| | (in thousands) | |
| Balance, beginning of year | $ 641 | $ 699 |
| New warranties | 316 | 974 |
| Payments | (258) | (355) |
| Adjustments | — | 605 |
| Balance, end of year | $ 699 | $1,923 |

## (4) 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.

*(b) Acquisition of Pro Duct Health, Inc.*

On November 30, 2001, the Company acquired Pro Duct, which developed proprietary ductal lavage technology to aid in breast cancer risk assessment. Using this technology, the Company introduced the FirstCyte Breast Test, which is currently used for women who are at high risk for breast cancer to detect atypical changes in cells lining the milk ducts, where an estimated 95 percent of all breast cancers originate. In connection with this acquisition, the Company issued an aggregate of approximately 5.0 million shares of the Company's common stock and $38.5 million in cash in exchange for all of the outstanding capital stock, vested options and warrants of Pro Duct. The Company accounted for the acquisition as a purchase in accordance with SFAS No. 141. The Company allocated approximately $56.0 million of the purchase price to in-process research and development projects, the cost of which was charged to expense in November 2001. The Company also allocated approximately $19.0 million to developed technology and know-how, which is being amortized over a period of 13 years. The excess of the purchase price over the fair value of tangible and identifiable intangible net assets of approximately $92.7 million as of November 30, 2001 was allocated to goodwill. Upon finalization of the purchase price allocation during 2002, goodwill was reduced by approximately $3.8 million as a result of a revision in certain estimates related to deferred taxes and the actual cost of the acquisition.

*(c) Termination of Digene Acquisition*

On June 24, 2002 the Company announced that the U.S. Federal Trade Commission ("FTC") had voted to seek to block Cytyc's proposed acquisition of Digene Corporation ("Digene"). The five-member commission authorized the staff to seek a court order to prevent the acquisition from being consummated. On June 30, 2002, the merger agreement was terminated and, accordingly, the Company expensed approximately $5.7 million in prepaid acquisition costs during 2002 to general and administrative expenses in the accompanying consolidated statement of income.

## (5) Allowance for Doubtful Accounts

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

| | December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| | (in thousands) | | |
| Balance, beginning of year | $1,134 | $1,510 | $1,987 |
| Amounts provided | 656 | 567 | 468 |
| Amounts written off | (280) | (90) | (352) |
| Balance, end of year | $1,510 | $1,987 | $2,103 |

## (6) Income Taxes

The Company, through its Cytyc Health Corporation subsidiary, has net operating losses for federal income tax purposes of approximately $16.3 million at December 31, 2002 that will expire at various dates beginning in 2017 and through 2020 if not utilized. The net operating loss 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 has research and development tax credit carryforwards for state tax purposes of approximately $3.4 million at December 31, 2002 that will expire at various dates beginning in 2003 and through 2020 if not utilized.

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

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| | (in thousands) | |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $16,797 | $ 5,698 |
| Research and development and other tax credit carryforwards | 7,834 | 3,449 |
| AMT tax credit carryforward | 1,019 | — |
| Capitalized research and development expenses | 2,742 | 1,032 |
| Amortization of acquisition-related charges | — | 1,481 |
| Warranty reserve | 268 | 729 |
| Deferred income | 200 | 295 |
| Depreciation | — | 1,269 |
| Bad debt reserve | 742 | 625 |
| Employee benefit related reserves | 1,388 | 471 |
| Other temporary differences | — | 32 |
| Deferred tax asset | 30,990 | 15,081 |
| Deferred tax liabilities: | | |
| Acquired know-how | (7,268) | (6,618) |
| Depreciation | (121) | — |
| Other | (116) | (120) |
| Deferred tax liabilities | (7,505) | (6,738) |
| Valuation allowance | — | — |
| Net deferred tax asset | $23,485 | $ 8,343 |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Current | | | |
| Federal | $— | $ 3,071 | $ 509 |
| Foreign | — | 41 | 44 |
| State | 853 | 1,447 | 3,370 |
| Total current | 853 | 4,559 | 3,923 |
| Deferred | | | |
| Federal | — | 20,320 | 24,241 |
| State | — | 194 | 1,199 |
| Total deferred | — | 20,514 | 25,440 |
| Total income tax provision | $853 | $25,073 | $29,363 |

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

| | December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Income tax provision at federal statutory rate | 35.0% | 35.0% | 35.0% |
| Research and development credit carryforwards | (3.3) | (2.8) | (0.3) |
| Research and development write-off related to Pro Duct acquisition | — | 51.8 | — |
| Changes in valuation allowance | (33.4) | (29.9) | — |
| State tax provision, net of federal benefit | 0.3 | 9.0 | 4.3 |
| Other | 3.5 | 3.4 | (1.0) |
| Effective tax rate | 2.1% | 66.5% | 38.0% |

## (7) Stockholders' Equity

### *(a) Common Stock Reserved*

As of December 31, 2002, the Company has reserved common stock for issuance as follows:

| | Number of Shares |
|---|---|
| Employee and Director stock incentive plans | 24,748,131 |
| Employee stock purchase plan | 896,469 |
| | 25,644,600 |

### *(b) Stock Repurchase Program*

In January 2002, the Company established a five-year stock repurchase program, with authority to spend up to $50,000,000. At the same time, the Board of Directors authorized the Company to repurchase under the program additional shares in an amount equal to the number of shares issued to the Company's stock option

holders upon exercise of their stock options. In July 2002, the Board of Directors authorized an increase in repurchase authority of $50,000,000, which is available until November 2007. In January 2003, the Board of Directors subsequently authorized an increase in repurchase authority of an additional $50,000,000, which is available through December 2003. Accordingly, the aggregate amount of the Company's common stock authorized for repurchase under the program is $150,000,000, plus the cost of purchasing additional shares in an amount equal to the number of shares issued to the Company's stock option holders upon exercise of their stock options. As of December 31, 2002, the Company had repurchased 9,623,677 shares under the program for cash totaling approximately $92,700,000, with an average price paid of $9.63 per share. As of December 31, 2002, all of the 9,623,677 repurchased common shares were held in treasury.

*(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.

*(e) Stock Warrant Issued to Quest Diagnostics, Inc.*

In January 2000, the Company entered into a multi-year supply and co-marketing agreement with Quest Diagnostics, Inc. ("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 on January 1, 2000 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 has amortized such amount as a reduction in revenue over the three-year term of the agreement ending December 31, 2002. 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. The agreement with Quest expired on December 31, 2002.

## (8) Stock Ownership Plans

*(a) Employee and Director Stock Incentive Plans*

The 1995 Stock Plan provides for the grant of various incentives, including nonqualified and incentive stock options, stock awards, and opportunities to make direct purchases of Company stock. The aggregate number of shares of common stock that may be issued pursuant to the 1995 Stock 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 Stock 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 Stock Plan. At December 31, 2002, 2,158,281 shares were available for future grant under the 1995 Stock Plan.

The 1995 Non-Employee Director Stock Option Plan (the "1995 Director Plan") provides for the issuance of options to purchase up to 1,500,000 shares of common stock. As of December 31, 2002, options to purchase 457,500 shares of common stock were outstanding under the 1995 Director Plan. No further options may be issued under the 1995 Director Plan.

The 2001 Non-Employee Director Stock Plan (the "2001 Director Plan") provides for the issuance of up to 4,000,000 shares of common stock to directors who are not employees of the Company in the form of either stock options or other equity awards. At December 31, 2002, 3,122,342 shares were available for future grant under the 2001 Director Plan.

The 1989 Stock Plan provides for the grant of various incentives, including nonqualified and incentive stock options, stock awards, and opportunities to make direct purchases of Company stock. As of December 31, 2002, options to purchase 180,862 shares of common stock were outstanding under the 1989 Stock Plan. No further options or awards may be issued under the 1989 Stock Plan.

The following schedule summarizes the activity under the Company's stock option plans for the three years ended December 31, 2002.

| | Number of Shares | Range of Exercise Prices | Weighted Average Exercise Price per share |
|---|---|---|---|
| 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 | 15,719,480 | 0.10–29.52 | 15.80 |
| Granted | 7,185,350 | 7.09–27.52 | 15.64 |
| Exercised | (1,696,817) | 0.10–21.92 | 6.19 |
| Canceled | (1,818,346) | 0.44–28.45 | 19.48 |
| Outstanding, December 31, 2002 | 19,389,667 | $0.14–$29.52 | $16.24 |
| Exercisable, December 31, 2002 | 7,964,057 | $0.14–$29.52 | $14.17 |
| Exercisable, December 31, 2001 | 4,913,064 | $0.10–$26.66 | $ 9.22 |
| Exercisable, December 31, 2000 | 2,832,494 | $0.10–$19.19 | $ 3.51 |

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

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number of Shares | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise price per share | Number of Shares | Weighted Average Exercise Price per share |
| $ 0.14–$4.50 | 2,669,383 | 5.24 | $ 3.26 | 2,433,110 | $ 3.27 |
| 4.71– 9.99 | 1,596,255 | 6.27 | 8.95 | 186,593 | 8.49 |
| 10.01–10.80 | 2,865,274 | 6.72 | 10.73 | 179,750 | 10.08 |
| 10.91–15.46 | 2,125,936 | 7.68 | 13.72 | 1,501,058 | 13.59 |
| 15.69–20.75 | 2,341,064 | 8.06 | 19.43 | 1,145,011 | 19.56 |
| 21.07–21.92 | 2,993,254 | 5.89 | 21.76 | 1,424,384 | 21.76 |
| 22.25–24.46 | 2,286,900 | 8.96 | 24.17 | 519,618 | 24.15 |
| 24.49–26.69 | 2,408,251 | 5.34 | 26.27 | 560,008 | 26.33 |
| 26.71–28.45 | 102,450 | 9.04 | 27.31 | 14,300 | 27.13 |
| 29.52–29.52 | 900 | 8.81 | 29.52 | 225 | 29.52 |
| $ 0.14–$29.52 | 19,389,667 | 6.72 | $16.24 | 7,964,057 | $14.17 |

As a result of the acquisition of Pro Duct (Note 4(b)), the Company recorded $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. Compensation expense related to these stock options totaled $55,000 and $342,000 during the years ended December 31, 2001 and 2002, respectively.

*(b) Employee Stock Purchase Plan*

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 average of the high and low 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. During 2002, 108,411 shares of common stock were issued at the purchase prices of $8.50 and $14.00 per share. As of December 31, 2002, 896,469 shares were available for future issuance under the 1995 Employee Stock Purchase Plan.

## (9) Commitments and Contingencies

*(a) Lease Commitments*

The Company leases its facilities and certain automobiles and office equipment under non-cancelable operating leases which have expiration dates ranging from 2003 through 2013.

At December 31, 2002, future minimum annual lease payments under these leases are as follows:

| | Amount (in thousands) |
|---|---|
| 2003 | $2,551 |
| 2004 | 2,195 |
| 2005 | 1,015 |
| 2006 | 719 |
| 2007 | 647 |
| Thereafter | 2,092 |
| | $9,219 |

Rent expense under operating leases totaled approximately $1,654,000, $1,759,000 and $2,165,000 in 2000, 2001 and 2002, respectively.

*(b) Long-Term Supply Contracts*

For reasons of quality assurance, sole source availability or cost effectiveness, certain key components and raw materials, including the proprietary filter material of the ThinPrep System, are available only from a sole supplier. Working closely with its suppliers, the Company has entered into certain long term supply contracts to assure continuity of supply while maintaining high quality and reliability. In certain of these contracts, a minimum purchase commitment has been established. At December 31, 2002, future supply commitments under these contracts are as follows:

| | Amount (in thousands) |
|---|---|
| 2003 | $ 3,000 |
| 2004 | 3,000 |
| 2005 | 3,000 |
| 2006 | 3,000 |
| 2007 | 3,000 |
| Thereafter | 15,000 |
| | $30,000 |

Payments under these contracts in 2000, 2001 and 2002 totaled approximately $1,500,000, $2,431,000 and $2,507,000, respectively.

*(c) 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 addition, the Company is the exclusive licensee of certain patented technology used in its FirstCyte Breast Test and pays a royalty equal to 3% of net sales of associated catheters. In connection with these licenses, royalty expenses for the years ended December 31, 2000, 2001 and 2002 were approximately $725,000, $1,114,000 and $1,351,000, respectively.

*(d) Litigation*

On December 13, 2002, a purported federal securities class action lawsuit was filed in the United States District Court for the District of Massachusetts against Cytyc and two of its officers, on behalf of a purported class of all persons who purchased the Company's common stock between July 25, 2001 and June 25, 2002. The complaint alleges that the defendants failed to disclose material facts and made materially misleading misstatements about the Company's historical and future financial performance. Since the initial suit was filed, five additional suits were filed in the same court, making the same or substantially similar allegations. Motions to consolidate the six actions into a single proceeding have been filed with the court. Cytyc believes that the allegations are without merit and intends to defend itself vigorously. Given the early stage and current status of the litigation, the Company is unable to reasonably estimate the ultimate outcome of this case, and accordingly, minimal expense has been recorded to date.

In September 1999, the Company filed suit against TriPath Imaging, Inc. ("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. Each party dismissed all pending claims and counterclaims against each other with 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 restrictions on selling such shares for a period of two years ending January 2003, as well as a receivable from TriPath.

The Company is also involved in various other lawsuits and claims arising in the normal course of business. Although the outcomes of these other lawsuits and claims are uncertain, management does not believe any of them will have a material adverse effect on the Company's business, financial condition or results of operations.

## (10) 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 $430,000, $777,000 and $969,000 related to the years ended December 31, 2000, 2001 and 2002, respectively.

(11) Summary of Quarterly Data (Unaudited)

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

| | 2002 | | | |
|---|---|---|---|---|
| | 1st | 2nd | 3rd | 4th |
| Net sales | $68,035 | $43,175 | $58,540 | $ 66,743 |
| Gross profit | 55,425 | 31,849 | 46,806 | 53,791 |
| Income (loss) from operations | 27,436 | (3,076) | 21,687 | 28,499 |
| Net income (loss) | 17,598 | (1,552) | 13,931 | 17,917 |
| Net income (loss) per share: | | | | |
| Basic | $ 0.14 | $ (0.01) | $ 0.12 | $ 0.16 |
| Diluted | $ 0.14 | $ (0.01) | $ 0.11 | $ 0.15 |

| | 2001 | | | |
|---|---|---|---|---|
| | 1st | 2nd | 3rd | 4th |
| Net sales | $47,467 | $52,997 | $57,249 | $ 63,280 |
| Gross profit | 38,626 | 43,558 | 46,786 | 51,855 |
| Income (loss) from operations | 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 | $ (0.31) |

## Board of Directors

**Patrick J. Sullivan, Chairman**
Chairman, President, and
Chief Executive Officer
*Cytyc Corporation*

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

**Walter E. Boomer**
Chairman 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
*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 University*

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

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

## Corporate Officers

**Patrick J. Sullivan**
Chairman, President, and
Chief Executive Officer

**Christopher A. Bleck**
Vice President, Commercial Operations

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

**Laura Deming**
Vice President, Engineering

**Anita Graham**
Vice President, Human Resources

**Daniel J. Levangie**
Executive Vice President
President and Chief Executive Officer
*Cytyc Health Corporation*

**James Linder, M.D.**
Vice President, Chief Medical Officer

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

**Victoria S. Robinson**
Vice President, Business Development

**Peter Rowden**
Vice President, Operations

**Leslie Teso-Lichtman**
Vice President, Controller

## Corporate Information

**Registrar & Transfer Agent**
EquiServe Trust Company
P.O. Box 43010
Providence, RI 02940-3010
Investor Relations Number: 781-575-3120
Internet Address: http://www.EquiServe.com

The transfer agent is responsible for maintaining Cytyc'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 Auditors**
Deloitte & Touche LLP
Boston, Massachusetts

**Legal Counsel**
Hogan & Hartson L.L.P.
Washington, D.C.

**Stock Symbol**
Cytyc common stock is listed on The Nasdaq Stock Market under the symbol "CYTC."

**Annual Meeting**
The annual meeting of shareholders will be held Thursday, May 15, 2003, at 9:30 a.m., at Cytyc Corporation, 85 Swanson Road, Boxborough, Massachusetts.

**Website**
Investors, shareholders, and security analysts seeking information should refer to the Company's website at www.cytyc.com. Electronic copies of SEC filings and recent news releases may also be found at the same online location.

**10-K**
A copy of Cytyc Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission is available free of charge upon request to Investor Relations, Cytyc Corporation, 85 Swanson Road, Boxborough, MA 01719.

Design: Benes Brand Imaging Group, Lexington, MA

Cytyc, the Cytyc logo, and ThinPrep are registered trademarks of Cytyc Corporation and FirstCyte is a trademark for which registration has been applied. All other trademarks and registered trademarks are the property of their respective owners.

CYTYC

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Telephone: (978) 263-8000 Fax: (978) 635-1033
www.cytyc.com

Forward-looking statements in this report are made pursuant to the provisions of Section 21E of the Securities Exchange Act of 1934. The Company's operating results and financial condition have varied and may in the future vary significantly depending on a number of factors. 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 plans and objectives for future management and operations, domestic and international marketing and sales plans, product plans and performance, research and development plans, regulatory uncertainties, potential savings to the healthcare system, management's assessment of market factors, as well as statements regarding the Company's strategy and plans, constitute forward-looking statements that involve risks and uncertainties. In some cases these forward-looking statements can be identified by the use of words such as "may," "will," "should," "expect," "project," "predict," "potential" or the negative of these words or comparable words. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from those statements. Risks detailed in the Company's filings with the Securities and Exchange Commission, including under the heading "Certain Factors Which May Affect Future Results" in its 2002 Annual Report on Form 10-K and its most recent Quarterly Report on Form 10-Q filed with the Commission, 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 Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they were made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any change in Company expectations or events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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